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UNITED STATES DISTRICT COURT
DISTRICT OF ALASKA

KODIAK AREA NATIVE ASSOCIATION,

Plaintiff,

vs.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY; RHODES PHARMACEUTICALS, L.P.; RHODES TECHNOLOGIES, INC.; CEPHALON, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. N/K/A NORAMCO, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; ENDO INTERNATIONAL PLC; PAR PHARMACEUTICAL, INC.; PAR

Case No.: 3:18-cv-00243-JWS

COMPLAINT

JURY TRIAL DEMANDED

PHARMACEUTICALS COMPANIES, INC. F/K/A PAR PHARMACEUTICAL HOLDINGS, INC.; ALLERGAN PLC F/K/A ACTAVIS PLC; ALLERGAN FINANCE LLC, F/K/A ACTAVIS, INC., F/K/A WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA, INC.; INSYS THERAPEUTICS, INC.; MALLINCKRODT PLC; MALLINCKRODT, LLC; SPECGX LLC; ABBOTT LABORATORIES; ABBOTT LABORATORIES, INC; AMNEAL PHARMACEUTICALS, INC F/K/A AMNEAL PHARMACEUTICALS, LLC; KVK-TECH, INC.; MCKESSON CORP.; CARDINAL HEALTH, INC.; CARDINAL HEALTH 110, LLC; AMERISOURCEBERGEN CORP.; ANDA, INC.; ANDA PHARMACEUTICALS, INC.; HENRY SCHEIN, INC., HENRY SCHEIN MEDICAL SYSTEMS, INC.; and JOHN & JANE DOES 1-100 INCLUSIVE,

Defendants.

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I. INTRODUCTION

1. An epidemic of opioid abuse is devastating the United States. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.[1] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[2]

2. The cause of this epidemic and the conditions for its acceleration were intentionally brought about by Defendants, who manufacture and distribute prescription opioids and who have made billions of dollars off the epidemic. The Defendants' unlawful marketing, sales, and distribution of prescription opioids resulted in the diversion, misuse, overdose and addiction described below.

3. Opioids are now the leading cause of accidental death in the U.S., surpassing deaths caused by car accidents. Opioid overdose deaths (which include prescription opioids as well as heroin) have risen steadily every year, from approximately 4,030 in 1999, to 15,597 in 2009, and to over 33,000 in 2015. In 2016, that toll climbed to 53,000.[3] The recent surge in opioid-related deaths involves prescription opioids, heroin, and other synthetic opioids.

4. More than half of all drug overdose deaths involve an opioid drug like those manufactured by Defendants,[4] and the increase in overdoses from non-prescription opioids is

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[1] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain - Misconceptions and Mitigation Strategies*, 374 N. Engl. J. Med. 1253 (2016), https://www.nejm.org/doi/full/10.1056/nejmra1507771 (last accessed August 6, 2018).

[2] *See* Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Engl. J. Med. 1480 (2016), https://www.nejm.org/doi/full/10.1056/NEJMsr1601307 (last accessed August 6, 2018).

[3] *Overdose Death Rates*, NIH National Institute on Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (revised Aug. 2018).

[4] *Understanding the Epidemic*, Centers for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Aug. 30, 2017) (last accessed August 6, 2018).

directly attributable to Defendants' success in expanding the market for opioids of any kind. In 2016, the number of overdose deaths involving opioids (including prescription opioids and illegal opioids like heroin and illicitly manufactured fentanyl) was 5 times higher than in 1999.[5]

5. Communities throughout the State of Alaska have been devastated by the opioid epidemic brought about by Defendants' conduct. On February 14, 2017, the Governor of the State of Alaska issued a Declaration of Disaster Emergency "in response to the growing number of overdoses attributed to opioid use," declaring that "an outbreak and a condition of public health disaster emergency exists statewide[.]"[6]

6. In 2012, Alaska's prescription opioid pain reliever overdose death rate was more than double the rate in the U.S. (10.5 vs. 5.1 per 100,000 persons, respectively), and Alaska's heroin-associated overdose death rate was over 50% higher than the national rate (3.0 vs. 1.9 per 100,000 persons, respectively).[7]

7. In 2013, Alaska's drug overdose death rate (14.4 per 100,000 persons) exceeded the national rate (13.8 per 100,000 persons).

8. Further, "the impact of the opioid crisis on American Indians and Alaska Natives is immense. The Centers for Disease Control and Prevention (CDC) reported that American Indians and Alaska Natives had the highest drug overdose death rates in 2015 and the largest percentage increase in the number of deaths over time from 1999-2015 compared to other

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[5] *Id.*
[6] Governor Bill Walker, State of Alaska Declaration of Disaster Emergency, https://gov.alaska.gov/wp-content/uploads/sites/5/2017021417_Opioid-Disaster-Declaration.pdf.
[7] State of Alaska Epidemiology Bulletin, DHHS, *Drug Overdose Deaths in Alaska, 2009-2015*, No. 6, March 24. 2016, http://www.epi.alaska.gov/bulletins/docs/b2016_06.pdf

racial and ethnic groups. During that time, deaths rose more than 500 percent among American Indians and Alaska Natives."[8]

9. Health care and social service providers throughout the State of Alaska, including Alaska Native tribal health organizations, have suffered costs as a direct result of this public health crisis. Plaintiff Kodiak Area Native Association (KANA), which provides health care and social services to Alaska Natives and local communities throughout the Koniag region of Alaska, has suffered loss of resources, economic damages, and increased costs in responding to the opioid epidemic.

10. The effects of the opioid crisis have been exacerbated by Defendants' efforts to conceal or minimize the risks of—and to circumvent or ignore safeguards against—opioid abuse. Instead of acting with reasonable care and in compliance with their legal duties, the Defendants intentionally flooded the market with opioids and pocketed billions of dollars in the process.

11. Defendants pursued a knowing, deliberate and deceptive campaign to persuade both doctors and patients that prescription opioids could and should be used long-term to treat chronic pain, and that they posed a low risk of addiction. Those claims were false and unsupported by scientific evidence,[9] and Defendants were aware of that at the time they were made. Nevertheless, through ongoing, fraudulent marketing, the Defendants transformed

[8] Cynthia Gunderson, *The IHS Launches New Opioids Website*, Indian Health Service, https://www.ihs.gov/newsroom/ihs-blog/july2018/the-ihs-launches-new-opioids-website/; *Illicit Drug Use, Illicit Drug Use Disorders, and Drug Overdose Deaths in Metropolitan and Nonmetropolitan Areas – United States*, 66 Morbidity and Mortality Wkly. Rep. 1, CDC (Oct. 20, 2017), https://www.cdc.gov/mmwr/volumes/66/ss/pdfs/ss6619.pdf

[9] *See* Letter from Vivek H. Murthy, U.S. Surgeon General, August 2016, *available at* http://turnthetiderx.org/ (last accessed August 10, 2018).

medical thinking about opioids. Defendants convinced doctors that the risk of addiction was modest and manageable, and outweighed by the benefits in reduced pain and improved quality of life for their patients; that it was safe to prescribe opioids previously used only for acute pain for long-term use; and that abuse-deterrent technology was effective in curbing opioid misuse and abuse.

12. Moreover, the prescription drug industry is required by statute and regulation to secure and monitor opioids at every step of the stream of commerce, thereby protecting opioids from theft, misuse, and diversion. The industry is also supposed to implement processes to alert it to "red flags" and stop suspicious or unusual orders by pharmacies, doctors, clinics, or patients. Defendants utterly failed to meet these obligations with respect to the opioid drugs they sold and distributed, despite their ability to do so.

13. Defendants, through their actions, thus fueled the opioid epidemic for their own financial gain, causing the United States to be flooded with opioids. Defendants created an environment where opioid diversion and abuse is rampant. Such diversion and abuse was an entirely foreseeable result of the Defendants' actions in intentionally creating an inflated market for dangerously addictive drugs through, in part, concealing the risks of addiction, and in shipping massive quantities of such drugs throughout the United States without taking reasonable and necessary steps to prevent diversion and misuse. These actions affect the State of Alaska overall, and the Koniag region.

14. Defendants' actions directly and foreseeably caused damages to KANA, including but not limited to the costs of (a) providing medical and therapeutic care, and prescription drug purchases (including prescribing and administering opioids based on

Defendants' widespread and pervasive campaign of misinformation); (b) treatment costs for patients suffering from opioid addiction or disease, overdose, or death, including unreimbursed costs; (c) counseling, treatment and rehabilitation services; (d) treatment of infants born with opioid-related medical conditions; (e) increased costs for social services including family and child welfare services, financial assistance, and employment and vocational training, among others; (f) increase costs for public safety; (g) lost opportunity costs; (h) increased administrative and human resource costs; and (i) the diversion of funding from other needed health care programs and services. These damages have been suffered and continue to be suffered directly by KANA.

15. KANA seeks injunctive relief, compensatory and statutory damages, as well as the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

II. THE PARTIES

A. The Plaintiff

16. Plaintiff KANA is a non-profit corporation providing health care and social services for Alaska Natives throughout the Koniag region of Alaska, with its principal place of business in Kodiak, Alaska. KANA works to provide integrated wellness services for the entire Kodiak Island community, with a focus on Alaska Native beneficiaries and implementation of Sugpiaq Alutiiq cultural values.

17. The KANA service area includes the City of Kodiak and six remote Alaska Native villages (Akhiok, Karluk, Larsen Bay, Old Harbor, Ouzinkie, and Port Lions) encompassing ten federally recognized Tribes of Kodiak Island. The City of Kodiak, situated at the northeastern tip of the island, is about 250 miles south of Anchorage. The city serves as the major supply and transportation hub for the archipelago's six village communities. Five are

located on Kodiak Island and one is on Spruce Island, on the northern end of the archipelago. Each of the rural communities can be reached only by aircraft or boat.

18. KANA provides health care services to American Indians and Alaska Natives, and to other eligible individuals within its service area, pursuant to Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. §§ 5301, *et seq.*, and the Alaska Tribal Health Compact. The ISDEAA authorizes tribes and tribal organizations like KANA to enter into contracts and compacts to assume responsibility to provide programs and services that the federal government would otherwise be obligated to provide for the benefit of American Indians and Alaska Natives. The Alaska Tribal Health Compact is the umbrella agreement, entered into between Alaska Native Tribes and tribal organizations in Alaska and the Indian Health Service (IHS) pursuant to Title V of the ISDEAA, that authorizes those tribes and tribal organizations to operate health and health-related programs formerly operated by the IHS in the State. In addition, each tribal co-signer to the Alaska Tribal Health Compact enters into separate funding agreements with the IHS that govern the scope of programs and services to be performed.

19. Over 99% of the IHS budget in Alaska is administered by tribes and tribal health programs under the Alaska Tribal Health Compact and other ISDEAA agreements. The Alaska Tribal Health System, which administers these programs and services, is composed of individual tribes and Tribal Health Organizations throughout the State, virtually all of whom are co-signers to the Alaska Tribal Health Compact.

20. KANA takes a patient-centered approach to wellness and provides medical, dental, and behavioral health care. In addition, KANA provides an array of community services,

including but not limited to infant learning and child advocacy; child welfare services under the Indian Child Welfare Act; Tribal Temporary Assistance for Needy Families (TANF); Women, Infants, and Children (WIC); employment training and services; Tribal Vocational Rehabilitation Program; economic development; and legal aid for qualifying patients.

21. KANA's community services are carried out pursuant to contracts with the Bureau of Indian Affairs under Title I of the ISDEAA, and pursuant to Public Law 102-477 (commonly referred to as the "477 Program"), which authorizes tribal governments to consolidate up to thirteen different programs from the Department of the Interior, Department of Labor, Department of Education, and Department of Health and Human Services into a single plan, approved by the Secretary of the Interior, to foster employment and economic development in Indian Country. The KANA 477 Program serves the region's Tribes with a variety of programs depending on the authorizing resolutions.

22. Further, KANA implements the Village Public Safety Officer Program (VPSO) as a means of providing rural Alaskan communities with needed public safety services at the local level to reduce the loss of life due to fires, drowning, lost person and the lack of immediate emergency medical assistance in rural communities. The VPSO Program was designed to train and employ individuals residing in the village as first responders to public safety emergencies such as search and rescue, fire protection, emergency medical assistance, crime prevention and basic law enforcement. Through KANA's partnership with the Alaska State Troopers (AST) and our local village and city councils, the VPSO presence on the island of Kodiak is viewed as a positive approach to public safety.

23. KANA serves high-needs populations with limited resources, including in remote areas where access to other service providers may not exist or would require a boat ride or flight. The diversion of funding to address a public health crisis like the opioid epidemic, including associated overhead and administrative costs, can have devastating impacts on an organization like KANA's ability to provide an adequate level of basic health care and other basic community services in these remote areas; to meet its obligations under federal laws and agreements with agencies of the federal government; and to carry out its organizational mission.

24. KANA has standing to recover damages incurred because of Defendants' actions and omissions. KANA has standing to bring all claims pled herein, including, *inter alia*, to bring claims under the federal RICO statutes, pursuant to 18 U.S.C. § 1961(3) ("persons" include entities which can hold legal title to property) and 18 U.S.C. § 1964 ("persons" have standing).

B. Manufacturer Defendants

25. The Manufacturer Defendants are identified below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

26. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of

business in Stamford, Connecticut. THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut. RHODES PHARMACEUTICALS, L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. RHODES TECHONOLOGIES, INC. is based in Coventry, Rhode Island, and operates as a subsidiary of Purdue Pharma L.P. Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Rhodes Pharmaceuticals, L.P., and Rhodes Technologies Inc. are referred to collectively as "Purdue."

27. Each Purdue entity acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

28. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,[10] and Targiniq ER in the U.S., including Alaska. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

29. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. (Teva Ltd.) is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. (Teva USA) is a wholly owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business

[10] Long-acting or extended release (ER or ER/LA) opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release (IR) opioids, last for approximately 4-6 hours.

in Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011. Teva Pharmaceuticals Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to collectively as "Cephalon."

30. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq and Fentora in the U.S., including in Alaska. The FDA approved Actiq and Fentora only for the management of breakthrough cancer pain in patients who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon pleaded guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

31. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Janssen Pharmaceuticals, Inc. formerly was known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. NORAMCO is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, and

J&J are referred to collectively as "Janssen". Upon information and belief, J&J controls the sale and development of Janssen Pharmaceutical's products and corresponds with the FDA regarding Janssen's products.

32. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including in Alaska, including the opioid Duragesic (fentanyl). Until January 2015, Janssen also developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

33. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO INTERNATIONAL PLC, has global headquarters in Dublin, Ireland and U.S. headquarters in Malvern, Pennsylvania. PAR PHARMACEUTICAL, INC. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. PAR PHARMACEUTICAL COMPANIES, INC. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are collectively referred to as "Par Pharmaceutical." Par Pharmaceutical was acquired by Endo International plc in September 2015 and is an operating company of Endo International plc. Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Endo International plc, and Par Pharmaceutical are referred to collectively as "Endo."

34. Endo develops, markets, and sells prescription drugs, including the opioids

Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States, including in Alaska. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, including in Alaska, by itself, through Par Pharmaceutical and through its subsidiary, Qualitest Pharmaceuticals, Inc.

35. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan plc in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired Actavis, Inc. in October 2012. The combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan plc (Allergan Finance, LLC, f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States, including in Alaska. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts, and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan Finance, LLC, Allergan plc,

Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to collectively as "Actavis."

36. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S., including in Alaska.

37. INSYS THERAPEUTICS, INC. is a Delaware corporation with its principal place of business in Arizona. Insys's principal product and source of revenue is Subsys, a transmucosal immediate-release formulation (TIRF) of fentanyl. Subsys was approved by the FDA solely for the treatment of breakthrough cancer pain. Insys promotes, sells, and distributes Subsys throughout the United States, including Alaska.

38. Insys's founder and owner was recently arrested and charged, along with other Insys executives, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. Insys specifically targeted at least one prescriber in Anchorage, Alaska, who was one of the top prescribers of Insys in the United States and whose license was ultimately suspended and then surrendered as a result of an investigation by the Alaska State Medical Board into his opioid prescribing practices.[11]

39. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.

[11] *See* Linette Lopez, *One company symbolizes everything sickening about the opioid crisis*, Business Insider, Apr. 13, 2017, *available at* http://www.businessinsider.com/opioid-crisis-and-insys-therapeutics-fentanyl-spray-2017-4. *See also*, ProPublica, Prescriber Checkup: Subsys, https://projects.propublica.org/checkup/drugs/8147 (last visited Aug. 10, 2018) (listing top prescribers of Subsys in the United States, including Dr. Ahmad of Anchorage, Alaska); ProPublica, Dollars for Docs: Talk With Your Doctor - Mahmood Ahmad, https://projects.propublica.org/docdollars/doctors/print/128721 (last visited Aug. 10, 2018) (listing payments from Insys to Dr. Ahmad).

MALLINCKRODT, LLC, is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly-owned subsidiary of Mallinckrodt, plc. SPECGX LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. Mallinckrodt, plc, Mallinckrodt, LLC, and SpecGX LLC are collectively referred to as "Mallinckrodt."

40. Mallinckrodt manufactures, markets, and sells drugs in the United States and Alaska, including generic oxycodone. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions. Mallinckrodt is one of the largest manufacturers of generic oxycodone. In July 2017, Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

41. ABBOTT LABORATORIES is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Defendant, ABBOTT LABORATORIES, INC., is an Illinois corporation with its principal place of business in Abbott Park, Illinois. ABBOTT LABORATORIES and ABBOTT LABORATORIES, INC. are referred to collectively as "Abbott."

42. Abbott was primarily engaged in the promotion and distribution of opioids nationally due to a co-promotional agreement with Defendant Purdue. Abbott promoted and distributed these opioids in the United States, including Alaska. Pursuant to an agreement with Purdue, between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue's opioid products.

43. Abbott, as part of the co-promotional agreement, helped make OxyContin into the largest selling opioid in the nation. Under the co-promotional agreement with Purdue, the more Abbott generated in sales, the higher the reward. Specifically, Abbott received twenty-five to thirty percent (25-30%) of all net sales for prescriptions written by doctors its sales force called on. This agreement was in operation from 1996-2002, following which Abbott continued to receive a residual payment of six percent (6%) of net sales up through at least 2006.

44. With Abbott's help, sales of OxyContin went from a mere $49 million in its first full year on the market to $1.6 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars. Abbott and Purdue's conspiring with pharmacy benefits managers to drive opioid use is well established.

45. As described in an October 28, 2016 article from Psychology Today entitled *America's Opioid Epidemic*:

> Abbott and Purdue actively misled prescribers about the strength and safety of the painkiller [OxyContin]. To undermine the policy of requiring prior authorization, they offered lucrative rebates to [intermediaries] and other pharmacy benefits managers, on condition that they eased availability of the drug and lowered co-pays. The records were part of a case brought by the state of West Virginia against both drug makers alleging inappropriate and illegal marketing of the drug as a cause of widespread addiction.
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> . . . .
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> One reason the documents are so troubling is that, in public at least, the drug maker was carefully assuring authorities that it was working with state authorities to curb abuse of OxyContin. Behind the scenes, however, as one Purdue official openly acknowledged, the drug maker was "working with Medco (PBM) [now Express Scripts] to try to make parameters [for prescribing] less stringent.[12]

[12] Christopher Lane, *America's Opioid Epidemic – Court released documents show drug makers blocked efforts to curb prescribing,* Psychology Today, Oct. 28, 2016, https://www.psychologytoday.com/blog/side-effects/201610/america-s-opioid-epidemic

46. AMNEAL PHARMACEUTICALS, INC. is a Delaware business entity with its principal place of business in New Jersey. Amneal Pharmaceuticals, Inc. was created when AMMEAL PHARMACEUTICALS, LLC merged with Impax. The merger was approved in 2018. Amneal Pharmaceuticals was headquartered in New Jersey. Amneal Pharmaceuticals, Inc., and Amneal Pharmaceuticals LLC, are collectively referred to as "Amneal." Amneal manufactures, promotes, sells, and distributes generic opioid products in the United States, including Alaska.

47. KVK-Tech, Inc. (KVK) is a Pennsylvania business entity with its principal place of business in Pennsylvania. KVK manufactures, promotes, sells, and distributes generic opioid products in the United States, including in Alaska.

48. Collectively, Purdue, Cephalon, Janssen, Endo, Actavis, Insys, Mallinckrodt, Amneal, and KVK are the "Manufacturer Defendants."

C. Distributor Defendants

49. Distributor Defendants are identified below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal law. KANA alleges the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing the United States, including Alaska.

50. CARDINAL HEALTH, INC. is a publicly traded company incorporated under the laws of Ohio and with a principal place of business in Ohio. CARDINAL HEALTH 110,

LLC., is based in Dublin, Ohio, and operates as a subsidiary of Cardinal Health, Inc. Cardinal Health, Inc., and Cardinal Health 110, LLC, are referred to collectively as "Cardinal." During all relevant times, Cardinal has distributed substantial amounts of prescription opioids to providers and retailers in Alaska and held a business and/or professional license in the State.

51. AMERISOURCEBERGEN CORPORATION (AmerisourceBergen) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in Pennsylvania. During all relevant times, AmerisourceBergen has distributed substantial amounts of prescription opioids to providers and retailers in Alaska and held a business and/or professional license in the State.

52. MCKESSON CORPORATION (McKesson) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in San Francisco, California. During all relevant times, McKesson has distributed substantial amounts of prescription opioids to providers and retailers in Alaska and held a business and/or professional license in the State.

53. ANDA, INC. is a Florida corporation with its principal office located in Weston, Florida. ANDA PHARMACEUTICALS, INC. was founded in 1992 and is based in Groveport, Ohio. Anda, Inc. and Anda, Pharmaceuticals Inc. are referred to collectively as "Anda". In October 2016, Defendant Teva acquired Anda from Allergan plc (i.e., Defendant Actavis), for $500 million in cash. At all times relevant, Anda distributed prescription opioids throughout the United States, including in Alaska.

54. HENRY SCHEIN, INC. is incorporated in Delaware, with its principal place of business in Melville, New York. Henry Schein, Inc. describes its business as providing a

comprehensive product and services offerings to integrated health systems, designed specifically for and focused exclusively on, the non-acute care space. Henry Schein, Inc. distributes, among other things, branded and generic pharmaceuticals to customers that include dental practitioners, dental laboratories, animal health practices and clinics, and office-based medical practitioners, ambulatory surgery centers, and other institutions. HENRY SCHEIN MEDICAL SYSTEMS, INC. (Henry Schein Medical) is a subsidiary of Henry Schein, Inc. that provides practice management, electronic medical records, and document management for medical groups. Henry Schein, Inc. and Henry Schein Medical Systems Inc. are referred to collectively as "Henry Schein."

55. In November of 2014, Henry Schein Medical and Cardinal Health entered into a strategic partnership, which consolidated Cardinal Health's physician office sales organization into Henry Schein Medical. Henry Schein took responsibility for serving physician offices, and through its "symbiotic" arrangement with Cardinal Health, gained access to over 25,000 physical offices as customer locations. As a result of this agreement, Henry Schein Medical added more than $300 million in annual sales. At all relevant times, Henry Schein was in the business of distributing, and redistributing, pharmaceutical products to consumers within the State of Alaska.

56. In 2015, Henry Schein reported that its sales reached a record $10.4 billion and that it had grown at a compound annual rate of approximately 16 percent since becoming a public company in 1995. Overall, it is the world's largest provider of health care products and services to office-based dental, animal health, and medical practitioners.

57. Collectively, Cardinal, AmerisourceBergen, McKesson, Anda, and Henry

Schein are the "Distributor Defendants".

58. The data that reveals and/or confirms the identity of each wrongful opioid distributor and the extent of their activity in Alaska is hidden from public view in the DEA's confidential ARCOS database. *See Madel v. U.S. Dep't of Justice*, 784 F.3d 448, 451 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will voluntarily disclose the data necessary to identify with specificity the transactions that will form the evidentiary basis for the claims asserted herein. *See id.* at 452-53.

59. Collectively, AmerisourceBergen, Cardinal, and McKesson dominate 85% of the market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal, McKesson, and AmerisourceBergen predecessors). Anda is the fourth largest distributor of generic pharmaceuticals in the United States.

D. John and Jane Does 1-100, inclusive

60. In addition to Defendants, the true names, roles, and/or capacities in the wrongdoing alleged herein of Defendants named John and Jane Does 1 through 100, inclusive, are currently unknown to Plaintiff, and thus are named Defendants under fictitious names as permitted by the Rules of this Court. Plaintiff will amend this Complaint and identify their true identities and their involvement in the wrongdoing at issue, as well as the specific causes of action asserted against them when they become known.

III. JURISDICTION AND VENUE

61. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action presents a federal question. This Court has supplemental jurisdiction over the state law causes of action under 28 U.S.C. § 1367 because the state law claims are part of the same case or controversy.

62. This Court independently has subject-matter jurisdiction over Plaintiff's state law claims under 28 U.S.C. § 1332(a)(2), because the matter in controversy exceeds the sum of $75,000 and no Defendant is a citizen of the same state as the Plaintiff.

63. This Court has personal jurisdiction over all Defendants because all Defendants have substantial contacts and business relationships with the State of Alaska, and have purposefully availed themselves of business opportunities within the State of Alaska, including by marketing, distributing, or selling prescription opioids within the State of Alaska.

64. This Court also has personal jurisdiction over all of the defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. *See, e.g., Iron Workers Local Union No. 17 Ins. Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (N.D. Ohio 1998); *Butcher's Union Local No. 498, United Food & Commercial Workers v. SDC Inv., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986).

65. Venue is proper in this Court under 28 U.S.C. § 1391(b) and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to this action occurred in this

judicial district and because all defendants are subject to this Court's exercise of personal jurisdiction.

IV. ADDITIONAL FACTUAL ALLEGATIONS

A. Background

66. The term "opioid" includes all drugs derived from the opium poppy. The United States Food and Drug Administration (FDA) describes opioids as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks." These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose, and death.[13]

67. Prescription opioids with the highest potential for addiction are listed under Schedule II of the Controlled Substances Act. This includes non-synthetic opium derivatives (such as codeine and morphine, also known generally as "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), and fully synthetic derivatives (such as fentanyl and methadone).

68. Historically, opioids were considered too addictive and debilitating for the treatment of chronic pain, like back pain, migraines, and arthritis. According to Dr. Caleb Alexander, director of Johns Hopkins University's Center for Drug Safety and Effectiveness, "[opioids] have very, very high inherent risks . . . and there's no such thing as a fully safe

[13] *See* U.S. Food & Drug Admin.,U.S. Dep't of Health and Human Servs., *Opioid Medications*, https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm (last updated Feb. 15, 2018).

opioid."[14]

69. Opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly over time no longer responds to the drug as strongly as before, thus requiring a higher dose to achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse.

70. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time, and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

B. The Manufacturer Defendants engaged in false, deceptive, and unfair marketing of opioids in order to create, and profit from, an inflated opioid market

71. To take advantage of the much larger and more lucrative market for chronic pain patients, the Manufacturer Defendants actively worked to change medical thinking about opioids.[15]

72. To that end, each Manufacturer Defendant developed a well-funded marketing scheme based on deception to persuade doctors, health care providers, and patients

[14] Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, The Center for Public Integrity, Dec. 15, 2016, *available at* https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution (last accessed Aug. 10, 2018).

[15] *See* Harriet Ryan et al., '*You want a description of hell?' OxyContin's 12-hour problem*, L.A. Times, May 5, 2016, *available at* http://www.latimes.com/projects/oxycontin-part1 (last accessed Aug. 10, 2018).

that opioids can and should be used for treatment of chronic pain, resulting in opioid treatment for a far larger group of patients who are much more likely to become addicted. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids while overstating the benefit of using them for chronic pain.

73. The deceptive marketing schemes included, among others, (1) false or misleading direct, branded advertisements; (2) false or misleading direct-to-physician marketing, also known as "detailing;" (3) false or misleading materials, speaker programs, webinars, and brochures; and (4) false or misleading unbranded advertisements or statements by purportedly neutral third parties that were really designed and distributed by the Manufacturer Defendants. In addition to using third parties to disguise the source of their misinformation campaign, the Manufacturer Defendants also retained the services of certain physicians, known as "key opinion leaders" or "KOLs" to convince both doctors and patients that opioids were safe for the treatment of chronic pain.

74. As part of these marketing efforts the Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels regarding the risks of using their drugs that: (1) downplayed the seriousness of addiction; (2) created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Manufacturer

Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

75. The Manufacturer Defendants have intentionally disseminated these common messages to reverse the medical understanding and public conceptions of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of the Manufacturer Defendants' marketing messages, through unbranded marketing and through industry-funded Front Groups. The messages were intended to, and did, reach throughout the medical community within the United States, including Alaska, in order to influence medical thinking and prescribing behavior nationwide.

76. These statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and the Center for Disease Control (CDC) based on that same evidence.

77. The Manufacturer Defendants began their marketing schemes decades ago and continue them today.

78. As discussed herein, the 2016 Guideline for Prescribing Opioids for Chronic Pain, published by the CDC, makes it patently clear that the Manufacturer Defendants' schemes were and continue to be deceptive.[16]

[16] Deborah Dowell, et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, 65 Morbidity & Mortality Wkly. Rep. 1 (2016) [hereinafter "2016 CDC Guideline"], *available at* https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

79. On information and belief, as a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States, including in Alaska.

80. For example, on information and belief, the Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be schooled in treating pain and the risks and benefits of opioids and therefore more likely to accept the Manufacturer Defendants' misrepresentations.

81. On information and belief, the Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, injured workers, and cancer patients, who tend to suffer from chronic pain.

82. The Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observed that existing evidence showed that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concluded that there are special risks of long-term opioid use for elderly patients and recommended that doctors use "additional caution and increased monitoring"[17] to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for posttraumatic stress disorder, which interact dangerously with opioids.

[17] *Id*. at 27.

83. To increase the impact of their deceptive marketing schemes, on information and belief, the Manufacturer Defendants coordinated and created unified marketing plans to ensure that their messages were consistent and effective across all their marketing efforts.

84. Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[18] In Alaska, two of the top ten most prescribed drugs are opioids.[19]

85. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors. . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[20]

86. The Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid epidemic and causing the harms and damages alleged herein.

1. The Manufacturer Defendants' used various types of Marketing Activities to disseminate false and misleading statements

87. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the United States.

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[18] *See* Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, Fortune, Nov. 9, 2011, *available at* http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/; David Crow, *Drugmakers hooked on $10bn opioid habit*, Fin. Times (Aug. 10, 2016), *available at* https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95.

[19] From March 2017 to February 2018, the top prescriptions included: #1. Hydrocodone/acetaminophen – pain medication and #4. Oxycodone/acetaminophen – pain medication. Kylie Walsh, *Most frequently prescribed medication in Alaska is an opioid*, State of Reform, Mar 27, 2018, https://stateofreform.com/featured/2018/03/most-frequently-prescribed-medication-in-alaska-is-an-opioid/ (last visited Aug. 10, 2018).

[20] Murthy, *supra* note 9.

They also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the United States, including Alaska.

a. Direct Marketing

88. The Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks: advertising campaigns and direct-to-physician marketing.

89. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, upon information and belief, the Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

90. A number of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. Some examples include:

a. Endo, on information and belief, has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

b. On information and belief, Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

91. Although Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, they continued to disseminate them elsewhere.

92. The direct advertising disseminated by the Manufacturer Defendants did not disclose studies that were unfavorable to their products, nor did they disclose that the lack of clinical evidence to support many of their claims.

b. "Detailing" and speaker programs

93. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through "detailers"—sophisticated and specially trained sales representatives who visited individual doctors and medical staff in their offices—and small group speaker programs.

94. The Manufacturer Defendants invested heavily in promoting the use of opioids for chronic pain through detailers and small group speaker programs.

95. Each Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, the Manufacturer Defendants spent in excess of $168 million in 2014 alone on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

96. On information and belief, these detailers have spread and continue to spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors, including doctors in Alaska. For example, on information and belief, the Manufacturer Defendants' detailers, over the past two years, continue to falsely and misleadingly:

a. Describe the risk of addiction as low or fail to disclose the risk of addition;

b. Describe their opioid products as "steady state"—falsely implying that these products are less likely to produce the highs and lows that fuel addiction—or as less likely to be abused or result in addiction;

c. Tout the effectiveness of screening or monitoring patients as a strategy for managing opioid abuse and addiction;

d. State that there is no maximum dose and that doctors can safely increase doses without disclosing the significant risks to patients at higher doses;

e. Promote the fictional concept of "pseudoaddiction" (this concept is described in paragraphs 115 and 150-52, *infra*);

f. State that patients would not experience withdrawal if they stopped using their opioid products;

g. State that their opioid products are effective for chronic pain without disclosing the lack of evidence for the effectiveness of long-term opioid use; and

h. State that abuse-deterrent formulations are tamper- or crush-resistant and harder to abuse or misuse.

97. Because these detailers must adhere to scripts and talking points drafted by the Manufacturer Defendants, it can be reasonably inferred that most, if not all, of the Manufacturer Defendants' detailers made and continue to make these misrepresentations to the thousands of doctors they have visited and continue to visit. The Manufacturer Defendants have not corrected this misinformation.

98. The Manufacturer Defendants' detailing to doctors was highly effective in the national proliferation of prescription opioids. On information and belief, the Manufacturer Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctors, allowing specific and individual targeting, customizing, and monitoring of their marketing.

99. The Manufacturer Defendants also identified doctors to serve, for payment and other remuneration, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Manufacturer Defendants. These speakers gave the false impression that they were providing unbiased and medically accurate presentations when they were, in fact, presenting a script prepared by the Manufacturer Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids.

100. Each Manufacturer Defendant devoted and continues to devote massive resources to direct sales contacts with doctors.

101. Marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. On information and belief, physicians who prescribe opioids frequently are generally more likely to have received a detailing visit. In some instances, physicians who prescribed opioids only infrequently received a detailing visit from a Manufacturer Defendant's detailer, and then prescribed only that Manufacturer Defendant's opioid products.

102. The FDA has cited at least one Manufacturer Defendant for deceptive promotions by its detailers and direct-to-physician marketing. In 2010, the FDA notified Actavis

that certain brochures distributed by Actavis were "false or misleading because they omit and minimize the serious risks associated with the drug, broaden and fail to present the limitations to the approved indication of the drug, and present unsubstantiated superiority and effectiveness claims." The FDA also found that "[t]hese violations are a concern from a public health perspective because they suggest that the product is safer and more effective than has been demonstrated."[21]

c. Unbranded advertising disseminated by seemingly independent third parties

103. The Manufacturer Defendants also deceptively marketed opioids through unbranded advertising—i.e., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. Yet, by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants coordinated and controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain.

104. The Manufacturer Defendants marketed opioids through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to

[21] Letter from Thomas Abrams, Director, Div. of Drug Marketing, Advertising & Communications, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), *available at* http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

105. The Manufacturer Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA.

106. The Manufacturer Defendants also spoke through a small circle of doctors—the KOLs—who, upon information and belief, were selected, funded, and elevated by the Manufacturer Defendants because their public positions supported the use of opioids to treat chronic pain.

107. Through their use of KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Manufacturer Defendants were able to exert control of each of these modalities through which doctors receive their information.

108. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants use to spread their false and misleading statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy.

109. For example, the New York Attorney General ("NY AG") found in its settlement with Purdue that through March 2015, the Purdue website "In the Face of Pain" failed to disclose that doctors who provided testimonials on the site were paid by Purdue,[22] and

[22] *See* New York State Office of the Att'y Gen., *A.G. Schneiderman Announces Settlement with Purdue Pharma That Ensures Responsible and Transparent Marketing Of Prescription Opioid Drugs By The Manufacturer* (Aug. 20, 2015), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent (last accessed Feb. 27, 2018).

concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

110. Pro-opioid KOLs have admitted to making false claims about the effectiveness of opioids. Dr. Russell Portenoy received research support, consulting fees, and other compensation from Cephalon, Endo, Janssen, and Purdue, among others. Dr. Portenoy admitted that he "gave innumerable lectures . . . about addictions that weren't true." His lectures falsely claimed that fewer than 1 percent of patients would become addicted to opioids. Dr. Portenoy admitted that the primary goal was to "destigmatize" opioids, and he conceded, "[d]ata about the effectiveness of opioids does not exist." According to Dr. Portenoy, "Did I teach about pain management specifically about opioid therapy, in a way that reflects misinformation? Well,. . . .I guess I did." Dr. Portenoy admitted that "[i]t was clearly the wrong thing to do."[23]

111. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentation, such as his claim that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low." He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely watched program, broadcast across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that the person is not going to become addicted."[24]

[23] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall St. J., Dec. 17, 2012, *available at* https://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (last accessed Aug. 10, 2018).

[24] Good Morning America (ABC television broadcast Aug. 30, 2010).

112. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of the American Academy of Pain Medicine (AAPM) in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous Continuing Medical Education or CMEs sponsored by Cephalon, Endo and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly $2 million from Cephalon).

113. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five-question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids.[25] The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and, for this reason, references to screening appear in various industry supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Manufacturer Defendants and those under their influence and control.

114. In 2011, Dr. Webster presented via webinar a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." On information and

[25] https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf

belief, Dr. Webster recommended the use of risk screening tools, urine testing and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths."[26]

115. Dr. Webster was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings that a patient was addicted to the drug, but as indications of undertreated pain. In Dr. Webster's description, when a patient presented such behaviors the only way to differentiate the two was to *increase the patient's dose of opioids*. As he and co-author Beth Dove wrote in their 2007 book Avoiding Opioid Abuse While Managing Pain—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."[27] Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[28]

116. The Manufacturer Defendants cited and promoted favorable studies or articles by their KOLs. By contrast, Manufacturer Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

117. On information and belief, the Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the

[26] *See* Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_continued&view=frontmatter&Itemid=303 &course=209 (last visited Aug. 10, 2018).
[27] Lynn R. Webster & Beth Dove, Avoiding Opioid Abuse While Managing Pain at 59 (2007).
[28] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/.

Manufacturer Defendants, these "Front Groups"—which include, but are not limited to, the American Pain Foundation (APF) (of which Dr. Portenoy was a member) and the AAPM—generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The evidence did not support these guidelines, materials, and programs at the time they were created, and the scientific evidence does not support them today. Indeed, they stand in marked contrast to the 2016 CDC Guideline.

118. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy.

119. On information and belief, these Front Groups also assisted the Manufacturer Defendants by responding to negative articles, by advocating against regulatory or legislative changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

120. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. A recent U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report reported that Purdue, Janssen, Insys, and other manufacturers made nearly $9 million in payments to 14 outside groups between 2012 and 2017, and that physicians affiliated with those groups have been paid more than $1.6 million since 2013.[29] The Report further noted: "Payments from Purdue totaling $4,153,554.33 account for

[29] U.S. Senate Homeland Sec. & Governmental Affairs Committee, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, (Feb. 12, 2018) at 1, *available at* https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf, (last accessed Aug. 10, 2018). On July 24, 2018, the Committee released a press release U.S. Senate Homeland Sec. & Governmental Affairs Committee, *McCaskill Amends Report After Finding Insys Therapeutics Failed to Report $100,000 in Contributions to Third Party Advocacy Group*, https://www.hsgac.senate.gov/media/minority-media/mccaskill-amends-report-after-finding-insys-therapeutics-

roughly half of the $9 million in funding to groups."[30] "Primarily due to large payments to the National Pain Foundation (now known as the Global Pain Initiative) and the U.S. Pain Foundation, Insys had the second-highest contribution total from 2012 to 2017, with $3,146,265 in payments."[31] During the investigation for the report, the Global Pain Initiative described $662,500 in contributions from Insys in 2013, 2015, 2016, and 2017—$100,000 more than Insys reported. In July 2018, Insys confirmed this additional $100,000 payment to the Global Pain Foundation.[32]

121. On information and belief, the Manufacturer Defendants exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, the Manufacturer Defendants made sure that the Front Groups would generate only the messages the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members—whether patients suffering from pain or doctors treating those patients.

122. Defendants Cephalon, Endo, Janssen and Purdue, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society (APS), American Geriatrics Society (AGS), the Federation of State Medical Boards (FSMB), American Chronic

failed-to-report-100000-in-contributions-to-third-party-advocacy-group (last visited Aug. 10, 2018). Fueling an Epidemic, Supplement to February 2018 Report, *available at* https://www.hsgac.senate.gov/imo/media/doc/SUPPLEMENT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf

[30] *Id.*

[31] *Id.*

[32] *Id.*

Pain Association (ACPA), the Center for Practical Bioethics (CPB), the U.S. Pain Foundation (USPF),[33] and the Pain & Policy Studies Group (PPSG).[34]

123. The most prominent of the Manufacturer Defendants' Front Groups was the APF, which, on information and belief, received more than $10 million in funding from opioid manufacturers (primarily from Endo and Purdue) from 2007 until it closed its doors in May 2012. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes—including death—among returning soldiers. APF also engaged in a significant multimedia campaign—through radio, television, and the internet—to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach citizens of all 50 states.

124. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. Upon information and belief, APF was often called upon to provide "patient representatives" for the Manufacturer Defendants' promotional activities, including for Purdue's Partners Against Pain and Janssen's Let's Talk Pain.

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[33] The U.S. Pain Foundation lists "Platinum," "Gold," and "Basic" corporate members—including Manufacturer Defendants like Abbott, Teva, Janssen (through J&J), Endo, Purdue, and Mallinckrodt—without indicating the level of donations required for each classification. They also list other Front Groups as members. U.S. Pain Foundation, Transparency, https://uspainfoundation.org/transparency/, (last accessed Aug. 10, 2018).

[34] *See generally, e.g.*, Letter from Sen. Ron Wyden, U.S. Senate Comm. on Finance, to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015), *available at* https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf, (last accessed Aug. 10, 2018).

125. However, APF functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

126. Organizations, including the U.S. Senate Finance Committee, began to investigate APF in 2012 to determine the links, financial and otherwise, between the organization and the opioid industry.[35] The investigation revealed that APF received 90 percent of its funding from the drug and medical-device industry, and "its guides for patients, journalists and policymakers had played down the risks associated with opioid painkillers while exaggerating the benefits from the drugs." Within days of the beginning of the Senate Finance Committee's investigation, APF dissolved "due to irreparable economic circumstances."

127. Another front group for the Manufacturer Defendants was the AAPM. With the assistance, prompting, involvement, and funding of the Manufacturer Defendants, the AAPM issued purported treatment guidelines, and sponsored and hosted medical education programs essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

128. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event, its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual

[35] Charles Ornstein & Tracy Weber, *Senate panel investigates drug companies ties to pain groups*, The Washington Post, May 8, 2012, *available at* https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-paid-groups/2012/05/08/gIQA2X4qBU_story.html (last accessed August 10, 2018).

event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. Defendant Teva is a current council member.[36]

129. Upon information and belief, AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Dr. Perry Fine of the University of Utah and Dr. Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

130. The Manufacturer Defendants were able to influence AAPM through both their significant and regular funding, and the leadership of pro-opioid KOLs within the organization.

131. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole

[36] AAPM, Corporate Relations Council Profiles, http://www.painmed.org/membercenter/corporate-relations-council-profiles/ (last accessed July 31, 2018).

consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained.[37]

132. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and concluding that the risk of addiction is manageable for patients regardless of past abuse histories.[38] The AAPM/APS Guidelines have been relied upon by doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants.

133. At least 14 of the 21 panel members, who drafted the AAPM/APS Guidelines, (including KOLs Dr. Portenoy and Dr. Fine), received support from Janssen, Cephalon, Endo, and Purdue. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members.

134. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids. The AAPM/APS Guidelines have been cited hundreds of times in academic and scientific literature, and were reprinted in the Journal of Pain. Further, the AAPM/APS

[37] *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997).
[38] Roger Chou, et al., *Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain*, 10 J. Pain 113 (2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4043401/.

Guidelines are referenced by third-party payors in determining whether they should cover treatments for specific indications.

135. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants' financial support to members of the panel. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the guidelines with doctors during individual sales visits.

136. On information and belief, the Manufacturer Defendants combined their efforts through the Pain Care Forum (PCF), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Abbott, Allergan, Cephalon, Endo, Insys, Janssen (through J&J), Purdue and Teva) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers. PCF also worked to address a lack of coordination among its members and developed cohesive industry messaging. Further, PCF worked to "influence legislation concerning prescription pain medications on both federal and state levels," with an average of six lobbyists in Alaska from 2006-2015.[39]

137. According to the Global Pain Initiative, Insys provided $50,000 in 2013 "to the organization without restrictions to start operations, in 4-separate payments of $12,500.00 each." In 2015, Insys reportedly provided three payments totaling $350,000 to "launch a race car

[39] Eugene Tauber, *Lobbyists hired by advocates for opioid manufacturers in every state*, The Morning Call, Sept. 17, 2016, http://www.mcall.com/news/local/data/mc-politics-of-pain-state-lobbyists-htmlstory.html (last accessed Aug. 10, 2018).

program 'Global Pain Initiative' to reach public for feedback," to "launch data discovery as to pain in the U.S. and move that to pain abroad," and to develop a "'digital data' collection tool for 'person centric' data."[40]

138. On information and belief, through Front Groups and KOLs, the Manufacturer Defendants wrote or influenced prescribing guidelines that reflected the messaging the Manufacturer Defendants wanted to promote rather than scientific evidence.

139. Through these means, and likely others still concealed, the Manufacturer Defendants collaborated to spread deceptive messages about the risks and benefits of long-term opioid use.

2. The Manufacturer Defendants' false and misleading statements understated the dangers of opioid drugs

140. To falsely assure physicians and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC.

141. The Manufacturer Defendants' misrepresentations reinforced each other and created the dangerously misleading impressions that (a) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (b) patients who displayed signs of addiction probably were not addicted (and likely suffered from pseudoaddiction) and, in any

[40] Fueling and Epidemic, Supplement to February 2018 Report, https://www.hsgac.senate.gov/imo/media/doc/SUPPLEMENT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf

event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive.

142. Some examples of these false claims include:

a. Actavis's predecessor caused a patient education brochure, Managing Chronic Back Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which suggests that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative prescriptions, or theft. This publication is available today.[41]

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated, "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

[41] APF, *Treatment Options: A Guide for People Living with Pain* (2007), *available at* https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last accessed Aug. 10, 2018).

Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated, "[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem."

e. Janssen reviewed and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen continues to maintain a website, *prescriberesponsibly.com* (last modified July 2, 2015) which claims that concerns about opioid addiction are "overestimated."[42]

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available

[42] *Available at* http://www.prescriberesponsibly.com/articles/opioid-pain-management (last accessed Aug. 10, 2018).

online.[43]

143. Consistent with the Manufacturer Defendants' published marketing materials, upon information and belief, detailers for the Manufacturer Defendants in Alaska and elsewhere have 1) minimized or omitted (and continue to minimize or omit) any discussion with doctors or their medical staff about the risk of addiction; 2) misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and 3) failed to correct the misrepresentations noted above.

144. The Manufacturer Defendants engaged in this campaign of misinformation in an intentional effort to deceive doctors and patients and thereby increase the use of their opioid products.

145. The Manufacturer Defendants' misrepresentations are contrary to longstanding scientific evidence.

146. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])."[44] The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder"[45] and that "continuing opioid therapy for [three] 3 months substantially increases risk for opioid use disorder."[46]

147. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR

[43] APF, *A Policymaker's Guide to Understanding Pain & Its Management*, at 6 (Oct. 2011), *available at* http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last accessed Aug. 10, 2018).
[44] 2016 CDC Guideline, *supra* note 16, at 15.
[45] *Id*. at 2.
[46] *Id*. at 25.

opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose and death."[47] According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.[48] The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

148. The Manufacturer Defendants have been, and are, aware that their misrepresentations about opioids are false.

149. The NY AG, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder."[49] Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with

[47] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing at 3 (Sept. 10, 2013), *available at* https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf (last accessed Aug. 10, 2018); Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan & Becker, LLP at 7 (Mar. 22, 2016), *available at* https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf (last accessed Aug. 10, 2018) (emphasis added).

[48] *Id.* at page 8 for both documents, respectively (emphasis added).

[49] Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc*. (Assurance No. 15-228), at 13, *available at* https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (last accessed August 10, 2018).

prolonged opioid medicines usually do not become addicted,"[50] but the NY AG found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York.[51]

150. The Manufacturer Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. The Manufacturer Defendants called this phenomenon "pseudoaddiction"—a term coined by Dr. J. David Haddox, who later became Vice President of Health Policy at Purdue, and popularized by Dr. Portenoy—and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

a. Cephalon and Purdue sponsored Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name", "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. The 2012 edition of *Responsible Opioid Prescribing* remains for sale online.[52]

b. On information and belief, Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is *under-treated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

[50] *Id*. at 6.
[51] *Id*. at 15.
[52] *See* Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Clinician's Guide* (2d ed. 2012).

c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug- seeking behaviors] in patients who have pain that has not been effectively treated."

e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse". In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long acting opioid.

151. Pseudoaddiction is fictional. The 2016 CDC Guideline rejects the concept of

pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[53] and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[54]

152. In connection with its settlement with the NY AG, Endo was forced to admit that the concept of pseudoaddiction was a sham. In finding that "[t]he 'pseudoaddiction' concept has never been empirically validated and in fact has been abandoned by some of its proponents," the NY AG, in its 2016 settlement with Endo, reported that despite the fact that Endo trained its sales representatives to use the concept of pseudoaddiction, "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'"[55]

153. The Manufacturer Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these

[53] 2016 CDC Guideline, *supra* note 16, at 13.
[54] *Id*. at 25.
[55] Assurance of Discontinuance, *supra* note 49, at 7.

doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

a. On information and belief, Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled "Pain Management Dilemmas in Primary Care: Use of Opioids", emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. On information and belief, Purdue sponsored a November 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. On information and belief, as recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients—and not opioids—are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

d. On information and belief, detailers for the Manufacturer Defendants have touted and continue to tout to doctors in Alaska the reliability and effectiveness of screening or monitoring patients as a tool for managing opioid abuse and addiction.

154. Once again, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported at the time they were made by the Manufacturer Defendants. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse—"for improving outcomes related to overdose, addiction, abuse, or misuse."[56] As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[57]

155. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

156. For example, on information and belief, a 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult,* claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days.

157. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.[58]

[56] 2016 CDC Guideline, *supra* note 16, at 11.
[57] *Id*. at 28 (emphasis added).
[58] APF, *Policymaker's Guide*, *supra* note 43 at 32.

158. The Manufacturer Defendants deceptively minimized the significant symptoms of opioid withdrawal, which, as explained in the 2016 CDC Guideline, include drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, tremor, and tachycardia (rapid heartbeat). The Marketing Defendants also grossly understated the difficulty of tapering, particularly after long-term opioid use.

159. Contrary to the Manufacturer Defendants' representations, the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days."[59] The Guideline further states that "more than a few days of exposure to opioids significantly increases hazards" and "each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit."[60]

160. The Manufacturer Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to the Manufacturer Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims are described below:

a. On information and belief, Actavis's predecessor created a patient brochure

[59] 2016 CDC Guideline, *supra* note 16, at 24.
[60] *Id.*

for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction."

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available online.[61]

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . .You won't 'run out' of pain relief."[62]

e. Janssen, on information and belief, sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its sales force distributed. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks

[61] APF, *Treatment Options, supra* note 41, at 12.
[62] Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K. Portenoy, M.D., ed., 2004).

of increased opioid dosages.

f. On information and belief, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.[63]

h. On information and belief, in 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available until at least 2012. The CME was edited by a KOL and taught that nonsteroidal anti-inflammatories (or NSAIDs) and other drugs, but not opioids, are unsafe at high dosages.

i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Front Group APF and others argued to the United States Court of Appeals for the Fourth Circuit that "there is no 'ceiling dose'" for opioids.[64]

j. On information and belief, Purdue's detailers have told doctors in Alaska that they should increase the dose of OxyContin, rather than the frequency of use,

[63] APF, *Policymaker's Guide*, *supra* note 43, at 32.

[64] Brief of the American Pain Foundation (APF), the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474, at 9 (4th Cir. Sept. 8, 2005).

to address early failure.

161. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains, "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that there are "increased risks for opioid use disorder, respiratory depression, and death at higher dosages."[65]

162. The Manufacturer Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can prevent and curb addiction and abuse.

163. These abuse deterrent formulations (AD opioids) purportedly are harder to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered with. Despite this, AD opioids can be defeated—often quickly and easily—by those determined to do so. The 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,"[66] noting that the technologies—even when they work—do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do not reduce the rate of misuse and abuse by patients who become addicted after using

[65] 2016 CDC Guideline, *supra* note 16, at 22-24.
[66] *Id.* at 22.

opioids long-term as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the Director of the CDC under President Obama, has further reported that his staff could not find "any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or deaths."[67]

164. Despite this lack of evidence, the Manufacturer Defendants have made and continue to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations to prevent or reduce abuse and addiction and the safety of these formulations.

165. For example, Endo has marketed Opana ER[68] as tamper- or crush-resistant and less prone to misuse and abuse even though: (1) on information and belief, the FDA warned in a 2013 letter that there was no evidence that Opana ER would provide a reduction in oral, intranasal or intravenous abuse; and (2) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Nonetheless, Endo's advertisements for Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse, and on information and belief, detailers for Endo have informed doctors that Opana ER is harder to abuse.

166. In its 2016 settlement with the NY AG, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The NY AG found those statements false and misleading because there was no difference in the ability to extract the

[67] Perrone et al., *supra* note 14.

[68] Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from the market. Press Release, "FDA requests removal of Opana ER for risks related to abuse," June 8, 2017, *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm (last accessed Feb. 27, 2018).

narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

167. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids, i.e., reformulated OxyContin and Hysingla. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, beginning in 2013, and continuing today, detailers from Purdue regularly use the so-called abuse deterrent properties of Purdue's opioid products as a primary selling point to differentiate those products from their competitors. Specifically, on information and belief, these detailers: (1) falsely claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (2) falsely claim that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (3) falsely claim Purdue's AD opioids are "safer" than other opioids; and (4) fail to disclose that Purdue's AD opioids do not impact oral abuse or misuse and that its abuse deterrent properties can be defeated.

168. These statements and omissions by Purdue are false and misleading. Purdue knew and should have known that reformulated OxyContin is not better at tamper resistance than the original OxyContin and is still regularly tampered with and abused. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, one-third of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other drugs such

as heroin.[69] Despite this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.[70]

169. The development, marketing, and sale of AD opioids is a continuation of the Manufacturer Defendants' strategy to use misinformation to drive profit. The Manufacturer Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more expensive than other opioid products even though they provide little or no additional benefit.

3. The Manufacturer Defendants' false and misleading statements overstated the benefits of chronic opioid therapy

170. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use.

171. The 2016 CDC Guideline makes clear that there is "insufficient evidence to determine long-term benefits of opioid therapy for chronic pain."[71] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled

[69] Cicero, Theodore J., and Matthew S. Ellis, *Abuse-deterrent formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned From Oxycontin* (2015) 72(5) JAMA PSYCHIATRY 424-430.
[70] *See* Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose epidemic*, Business Insider, Mar. 14, 2016, *available at* http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3 (last accessed Feb. 27, 2018).
[71] 2016 CDC Guideline, *supra* note 16, at 19.

randomized trials ≤ 6 weeks in duration)"[72] and that other treatments were more or equally beneficial and less harmful than long-term opioid use.

172. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[73]

173. Despite this, the Manufacturer Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the Manufacturer Defendants failed to correct these false and misleading claims, they continue to make them today.

174. For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims are described below:

a. On information and belief, Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

[72] *Id*. at 15.
[73] Letter from Janet Woodcock to Andrew Koldny, *supra* note 47, at 9.

c. On information and belief, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

d. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

e. APF's *Treatment Options: A Guide for People Living with Pain*, sponsored by Cephalon and Purdue, counseled patients that opioids "give [pain patients] a quality of life we deserve." This publication is still available online.[74]

f. On information and belief, Endo's NIPC website *painknowledge.com* claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy.

g. On information and belief, Janssen sponsored, funded, and edited a website,

[74] APF, *Treatment Options*, *supra* note 41, at 15.

Let's Talk Pain, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

h. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients.[75] The Policymaker's Guide is still available online today.

i. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue's opioids, to chronic pain patients' "quality of life," and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.[76]

175. The above claims find no support in the scientific literature. The 2016 CDC Guideline approved by the FDA concluded "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely."[77] The CDC reinforced this conclusion throughout its 2016 Guideline:

a. "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . .

[75] APF, *Policymaker's Guide, supra* note 43, at 29.
[76] Matthew Harper, *Why Supposedly Abuse-Proof Pills Won't Stop Opioid Overdose Deaths*, Forbes (Apr. 17, 2015), *available at* https://www.forbes.com/sites/matthewherper/2015/04/17/why-supposedly-abuse-proof-pills-pill-wont-stop-opioid-overdose-deaths/#6a4e41f06ce1 (last accessed Aug. 13, 2018).
[77] 2016 CDC Guideline, *supra* note 16, at 20. (Emphasis added).

."[78]

b. "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."[79]

c. "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."[80]

176. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[81] As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

177. The 2016 CDC Guideline was not the first time a federal agency repudiated the Manufacturer Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities,

[78] *Id*. at 15.
[79] *Id*. at 18.
[80] *Id*. at 18-19.
[81] *Id*. at 20.

or enjoyment of life."[82] Upon information and belief, in 2008, the FDA sent a warning letter to an opioid manufacturer, making it publicly clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."[83]

178. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like over-the-counter NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, the Manufacturer Defendants frequently pointed to the lack of a ceiling dosage for opioids in contrast to NSAIDs. The Manufacturer Defendants deceptively described the risks from NSAIDs while failing to disclose the risks from opioids, and they overstated the number of deaths from NSAIDS. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. For example, the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

179. For example, Purdue, with assistance from Abbott between 1996 and 2002, misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. OxyContin does not last for 12 hours—a fact that Purdue has known at all times relevant to this action.[84] Upon information and belief, Purdue's own research

[82] Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC, Feb. 18, 2010, at 5, *available at* https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf (last accessed Aug. 10, 2018).
[83] Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008).
[84] *See* Ryan et al., *supra* note 15.

shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

180. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm.

181. Despite this, on information and belief, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate or safe.[85] As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales

[85] *See* Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay $425 million & Enter Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html (last accessed Aug. 10, 2018).

representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer- related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.

b. Upon information and belief, Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

c. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News—three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain"—and not just cancer pain.

182. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

183. Likewise, Insys aggressively and misleadingly promoted Subsys—that has been approved by the FDA only for management of breakthrough pain in adult cancer patients—as safe and appropriate for non-cancer pain such as neck and back pain, without disclosing the lack of approval or evidence for such uses, and misrepresented the appropriateness of Subsys for treatment of those conditions. Insys specifically targeted doctors other than oncologists, including by paying them through its fraudulent speaker program (discussed below), and training its sales force to encourage physicians to prescribe Subsys for patients who were suffering from non-cancer pain.[86]

4. The Manufacturer Defendants knew that their representations were false and misleading, and fraudulently concealed their conduct to avoid detection

184. As alleged herein, the Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. The Manufacturer Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out above and alleged throughout this Complaint.

185. On information and belief, the Manufacturer Defendants coordinated their messaging through national and regional sales and speaker trainings and coordinated advertisements and marketing materials.

186. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for

[86] Specific instances of this conduct are described in a complaint filed by the Department of Justice, intervening in five lawsuits that accuse Insys of violating the False Claims Act and other federal laws in connection with the marketing of Subsys. United States Complaint in Intervention, No. 2:13-cv-05861 (C.D. Cal. Apr. 13, 2018), *available at* https://www.justice.gov/opa/press-release/file/1063051/download.

chronic pain even though they knew that their misrepresentations were false and misleading.

187. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The Manufacturer Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations. Defendants Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

188. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and misleading statements about the risks and benefits of long-term opioid use for chronic pain.

189. The Manufacturer Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and

"educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not made public.

190. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks.

191. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. Because the Manufacturer Defendants' misinformation campaign was so pervasive, the lack of support for the Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions.

192. Upon information and belief, the use of opioids by individuals served by KANA who were addicted or who did not have a medically necessary purpose would not have occurred without the activities of Manufacturer Defendants alleged in this Complaint.

5. Defendant Insys went beyond false and misleading marketing to bribe physicians and lie to insurers to obtain preauthorization for reimbursement

193. Defendant Insys paid prescribers for fake speakers' programs in exchange for prescribing its product, Subsys. Insys's schemes resulted in countless speakers' programs at which the designated speaker did not speak, and, on many occasions, speaker programs at which the only attendees at the events were the speaker and an Insys sales representative. In other words, Insys went beyond just promoting speakers who would, in turn, promote their product: it was a pay-to-prescribe program in which Insys used speakers' programs as a front to pay for prescriptions and to push opioids onto patients who did not need them. These activities are outlined in a complaint filed by the Department of Justice, intervening in five lawsuits that accuse Insys of violating the False Claims Act in connection with the marketing of Subsys.[87]

194. According to publically available information, payments by Insys included over $150,000 to Dr. Mahmood Ahmad between 2013 and 2016 for promotional speaking, consulting, and other payments.[88] Dr. Ahmad operated a pain clinic in Anchorage, Alaska, until his license was suspended by the Alaska State Medical Board due to his dangerous opioid prescribing practices.[89]

195. In addition to its fraudulent "speaker program," Insys established an internal

[87] Press Release, Department of Justice, *United States Intervenes in False Claims Act Lawsuits Accusing Insys Therapeutics of Paying Kickbacks and Engaging in Other Unlawful Practices to Promote Subsys, A Powerful Opioid Painkiller* (May 15, 2018), *available at* https://www.justice.gov/opa/pr/united-states-intervenes-false-claims-act-lawsuits-accusing-insys-therapeutics-paying (providing a link to recently unsealed complaint) (last visited Aug. 10, 2018).

[88] ProPublica, Dollars for Docs: Talk With Your Doctor, *supra*, note 11.

[89] Michelle Theriault Boots, *Medical board suspends license of doctor accused of running painkiller 'pill mill' clinic in Anchorage*, Anchorage Daily News (f/k/a Alaska Dispatch News), May 24, 2016, https://www.adn.com/alaska-news/2016/05/23/medical-board-suspends-license-of-doctor-accused-of-running-painkiller-pill-mill-clinic-in-anchorage/ (last visited August 10, 2018).

unit, sometimes referred to as the Insys Reimbursement Center, to facilitate the process of obtaining prior authorization of Subsys prescriptions, which is required by many insurers. Insys employees in the Insys Reimbursement Center employed fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading information to insurers regarding patients' diagnoses and medical conditions. Insys employees also lied about their employer, falsely claiming or implying that they were employed by the physician or nurse practitioner that had prescribed Subsys. Specific examples of this fraudulent conduct are also outlined in the United States' Complaint in Intervention against Insys.[90]

196. All of these actions were intended to, and had the effect of, pushing Insys's dangerous opioid products onto patients who did not need it.

C. All Defendants assisted in the creation of a nationwide, illicit market for opioids by failing to uphold their legal duties to prevent unlawful diversion

197. In addition to the allegations above, all Defendants played a role in the creation of an illicit market for prescription opioids, including in Alaska, further fueling the opioid epidemic by failing to fulfill their legal duties to prevent diversion.

198. Opioid "diversion" occurs whenever the supply chain of prescription opioids is broken, allowing drugs to be transferred from a legitimate channel of distribution or use to an illegitimate channel of distribution or use. Opioid diversion occurs at an alarming rate in the United States, and diverted prescription opioids predictably flow across State lines and between jurisdictions throughout the country.

[90] *Supra*, note 86.

199. Each participant in the supply chain, including each Defendant, has a common law duty to prevent diversion by using reasonable care under the circumstances. This includes a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

200. In addition to their common law duties, Defendants are subject to the statutory requirements of the Controlled Substances Act, 21 U.S.C. §§ 801, *et seq*. (the "CSA"), and its implementing regulations. Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled substances] out of legitimate channels into the illicit market." H.R. Rep. No. 91-1444, 91st Cong., Sess. 1 (1970), reprinted in U.S.C.C.A.N. 4566, 4572.

201. The CSA imposes a legal framework for the distribution and dispensing of controlled substances. This framework acts as a system of checks and balances from the manufacturing level through delivery of the controlled substance to the patient or ultimate user.

202. Every person or entity that manufactures, distributes, or dispenses opioids must obtain a registration with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA.

203. All opioid distributors are required to maintain effective controls against opioid diversion. They are required to create and use a system to identify and report to law enforcement downstream suspicious orders of controlled substances, such as orders of unusually large size, orders that are disproportionate, orders that deviate from a normal pattern, and/or

orders of unusual frequency. To comply with these requirements, distributors must know their customers, must conduct due diligence, must report suspicious orders, and must terminate orders if there are indications of diversion.

204. Under the CSA, anyone authorized to handle controlled substances must track shipments. The DEA's Automation of Reports and Consolidation Orders System (ARCOS) is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from the point of manufacture through distribution to the point of sale. ARCOS accumulates data on distributors' controlled substances and transactions, which are then used to identify diversion. Each person or entity registered to distribute "ARCOS reportable" controlled substances, including opioids, must report each acquisition and distribution transaction to the DEA. *See* 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each registrant must also maintain a complete, accurate and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of.

205. Each registrant must also comply with the security requirements to prevent diversion set forth in 21 C.F.R. § 1301.71.

1. The Distributor Defendants' failure to prevent diversion

206. The DEA has provided guidance to distributors on how to combat opioid diversion. On information and belief, since 2006 the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, due diligence, and regulatory responsibilities. On information and belief, the DEA also provides distributors with data on controlled substance distribution patterns and trends, including data on the volume and frequency of orders and the percentage of controlled versus non-controlled purchases. On information and

belief, the DEA has also hosted conferences for opioid distributors and has participated in numerous meetings and events with trade associations.

207. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring and the responsibilities and obligations of registrants to prevent diversion.

208. As part of the legal obligation to maintain effective controls against diversion, the distributor is required to exercise due care in confirming the legitimacy of each and every order prior to filling. Circumstances that could be indicative of diversion include ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; ordering a disproportionate amount of controlled substances versus non-controlled prescription drugs; ordering excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors.

209. Suspicious orders must be reported when discovered. Registrants must perform an independent analysis of a suspicious order prior to the sale to determine if the controlled substances would likely be diverted, and filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility.

210. On information and belief, the Distributor Defendants' own industry group, the Healthcare Distribution Management Association (HDMA), now known as the Healthcare Distribution Alliance (HDA), published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" emphasizing the critical role of each member of the supply chain in distributing controlled substances. These industry

guidelines stated: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."[91]

211. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

212. These assurances, on their face, of identifying and eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to take reasonable measures to do just that.

213. Despite their duties to prevent diversion, the Distributor Defendants have knowingly, recklessly, or negligently allowed diversion.[92] The DEA has repeatedly taken action to attempt to force compliance, including 178 registrant actions between 2008 and 2012, 76 orders to show cause issued by the Office of Administrative Law Judges, and 41 actions involving immediate suspension orders.[93] The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

a. In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the]

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[91] *HDMA Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App. B at 1).

[92] Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, The Wash. Post, Oct. 15, 2017, *available at* http://wapo.st/opioids?tid=ss_mail (last accessed Aug. 10, 2018); Lenny Bernstein *et al*., *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post, Oct. 22, 2016, *available at* http://wapo.st/2etAUdQ?tid=ss_mail&utm_term=.96341c37bdb5 (last accessed Aug. 10, 2018).

[93] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (May 2014), *available at* https://oig.justice.gov/reports/2014/e1403.pdf (last accessed Aug. 10, 2018).

DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson was fined $150,000,000.[94]

b. McKesson has a history of repeatedly failing to perform its duties. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the Country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer.

c. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion.

d. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion.

e. On December 7, 2007, the DEA issued an Order to Show Cause and

[94] Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp., at 3 (Jan. 17, 2017), *available at* https://www.justice.gov/opa/press-release/file/928476/download (last accessed Feb. 27, 2018).

Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion.

f. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion.

g. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States.[95]

h. On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion.

i. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states.

j. In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the CSA.[96]

k. On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or

[95] Lenny Bernstein and Scott Higham, *Cardinal Health fined $44 million for opioid reporting violations*, The Wash. Post, Jan. 11, 2017, *available at* http://wapo.st/2j8VHEc?tid=ss_mail&utm_term=.e5b03bdcdffa (last accessed Feb. 27, 2018).

[96] Press Release, United States Dep't of Justice, *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act* (Dec. 23, 2016), *available at* https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act (last accessed Aug. 10, 2018).

cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

l. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.

m. In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.

n. In 2016, five drug wholesalers, including Anda, agreed to a $4.2 million settlement in connection with a lawsuit alleging that they shipped an excessive number of prescription opioids in West Virginia.[97] Anda's share is $1.9 million.

214. Although distributors have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

215. The Distributor Defendants' failure to prevent the foreseeable consequences of opioid diversion created an enormous black market for prescription opioids, which market extends to the geographic area, communities, and eligible patient population served by KANA.

[97] AP, *5 drug wholesalers agree to settle pill shipment lawsuit*, The Washington Times, June 23, 2016, https://www.washingtontimes.com/news/2016/jun/23/2-more-drug-wholesalers-settle-in-pill-shipment-la/ (last accessed Aug. 10, 2018); Thomas Sullivan, *More Opioid Pill Shipment Settlements*, Policy & Medicine, May 5, 2018 https://www.policymed.com/2016/07/more-opioid-pill-shipment-settlements.html (last accessed Aug. 10, 2018).

Each Distributor Defendants knew or should have known that a large amount of the opioids they distributed were not being consumed for medical purposes and that the amount of opioids distributed was far in excess of what could be consumed for medically necessary purposes.

216. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

217. On information and belief, the compensation the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

218. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the market in the United States and Alaska with highly addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

219. It is reasonably foreseeable to the Distributor Defendants that, when

unintended users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses, and death. It is also reasonably foreseeable that many of these injuries will be suffered by individuals served by health and social services providers like KANA, and that the costs of these injuries will thus be borne by KANA.

220. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid epidemic, and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

221. The Distributor Defendants were aware of widespread prescription opioid abuse throughout the United States and in Alaska, but, on information and belief, they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in specific geographic areas, in such quantities, and with such frequency, that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

222. The use of prescription opioids by individuals served by KANA who were addicted or who did not have a medically necessary purpose could not occur without the knowing cooperation and assistance of the Distributor Defendants. If the Distributor Defendants adhered to effective controls to guard against diversion, KANA and the populations they serve would have avoided significant injury.

223. The Distributor Defendants made substantial profits over the years based on the diversion of opioids into the United States and Alaska. The Distributor Defendants knew that due to diversion into Alaska, KANA and other tribal organizations providing health care and

social services to Alaska Natives throughout the State would be unjustly forced to bear the costs of these injuries and damages.

224. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids throughout the United States and in Alaska showed an intentional or reckless disregard for the safety of the public and the eligible patient population served by KANA. Their conduct poses a continuing threat to this population, and therefore to KANA.

2. The Manufacturer Defendants' failure to prevent diversion

225. The same legal duties to prevent diversion and to monitor, report, and prevent suspicious orders of prescriptions opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under federal law.

226. Like the Distributor Defendants, the Manufacturer Defendants are required to design and operate a system to detect suspicious orders, and to report such orders to law enforcement. *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823. The Manufacturer Defendants have not done so.

227. On information and belief, for over a decade the Manufacturer Defendants have been able to track the distribution and prescribing of their opioids down to the retail and prescriber level. Thus, the Manufacturer Defendants had actual knowledge of the prescribing practices of doctors, including red flags indicating diversion. The Manufacturer Defendants did not report those red flags, nor did they cease marketing to those doctors. Like the Distributor Defendants, the Manufacturer Defendants breached their duties under federal law.

228. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. In addition

to tracking prescriptions, the Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

229. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law (21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(a)(1)), fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[98] Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report suspicious orders for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[99] Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the

[98] *See* Press Release, U.S. Dep't of Justice, *Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations* (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

[99] *Id.* (internal quotations omitted).

standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."[100]

230. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Through its extensive network of sales representatives, Purdue had and continues to have knowledge of the prescribing practices of thousands of doctors and could identify doctors who displayed red flags for diversion such as those whose waiting rooms were overcrowded, whose parking lots had numerous out-of-state vehicles, and whose patients seemed young and healthy or homeless.

231. Using this information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs.[101] Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused.

232. In an interview with the Los Angeles Times,[102] Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to

[100] Administrative Memorandum of Agreement between the United States Dep't of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download.

[101] Scott Glover and Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, L.A. Times, Aug. 11, 2013, *available at* http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811 (last accessed Aug. 13, 2018).

[102] Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, L.A. Times, July 10, 2016, *available at* http://www.latimes.com/projects/la-me-oxycontin-part2/ (last accessed Aug. 13, 2018).

take action—even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

233. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015, Purdue's sales representatives, at various times, failed to timely report suspicious prescribing and continued to detail those prescribers even after they were placed on a "no-call" list."[103]

234. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in a Los Angeles Times article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it."[104] The NY AG's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

235. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY AG found that Endo failed to require sales representatives to report signs of abuse, diversion,

[103] *See* Assurance of Discontinuance, *In re Purdue Pharma L.P.* (Assurance No. 15-151), *available at* https://ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf (last visited Aug. 13, 2018).
[104] Scott Glover and Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, L.A. Times, August 11, 2013, *available at* http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811 (last accessed Aug. 13, 2018).

and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegal prescribing of opioids, those representatives could have recognized potential signs of diversion and reported those prescribers but failed to do so.

236. On information and belief, the other Manufacturer Defendants have engaged in similar conduct in violation of their responsibilities to prevent diversion.

237. The Manufacturer Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into the geographic area, communities, and eligible patient population served by KANA.

3. The Defendants' actions in inflating and flooding the market with prescription opioids, and in failing to prevent diversion, foreseeably led to the flow of such drugs between jurisdictions

238. While each of the Defendants do business in the State of Alaska, their activity in that State is not the only conduct that is relevant to the creation of the opioid epidemic in that State or to the injury suffered by KANA. Nor does prescription and other specific data from any particular jurisdiction necessarily capture the full scope of the misuse, oversupply, and diversion problem in that area. That is because the Defendants' actions nationwide foreseeably fueled a widespread epidemic in which diverted prescription opioid pills were and are trafficked between jurisdictions to meet the demand created by the Defendants' promotion and distribution of highly

addictive, controlled substances. The trafficking of prescription opioids between jurisdictions, which has been documented by law enforcement across the country, was an entirely foreseeable consequence of the Defendants' actions, and Defendants were in fact aware of and profited from it.

239. In one widely-reported example, 1.1 million OxyContin pills were transported from the Lake Medical pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington, where they were sold on the black market. Couriers drove the pills up I-5 through California and Oregon, or flew from Los Angeles to Seattle. The Everett-based dealer who received and sold the pills wore a diamond necklace in the shape of the West Coast states, with a trail of green gems—the color of 80-milligram OxyContin pills—connecting Los Angeles and Washington State. At the time, Purdue was aware of the massive and highly suspicious quantities of prescriptions written by Lake Medical's physicians and filled by area pharmacies, but it did not alert law enforcement until years later.[105] Other such pipelines exist or have existed between other jurisdictions throughout the United States.

240. The opioid epidemic in Alaska, and in the geographic area served by KANA, is sustained, in part, by the flow of prescription opioids into the State from other jurisdictions. The most recent Alaska State Troopers Annual Drug Report notes that drug trafficking organizations ("DTOs") from the Lower 48 have infiltrated Alaska and that "the source of the illicit substances peddled by the major DTOs comes from outside the state."[106] "[H]eroin,

[105] *See* Harriet Ryan et al., *How black-market OxyContin spurred a town's descent into crime, addiction and heartbreak*, L.A. Times (July 10, 2016), *available at* http://www.latimes.com/projects/la-me-oxycontin-everett/.
[106] Alaska State Troopers Annual Drug Report (2016), https://dps.alaska.gov/getmedia/f259530b-5277-408e-9d45-4999958fe530/2016-Annual-Drug-Report-6-28-17final;.aspx.

prescription opioids, and other drugs make their way to rural Alaska via transport that is not subject to the same level of federal security/inspection as that of major commercial airlines."[107] This includes trafficking by way of mail, bush airlines, small planes, boats and even Alaska Marine Highway System and inter-island ferries, where a recent sweep of three terminals (including the terminal in Kodiak) by the United States Coast Guard and the Alaska State Troopers resulted in the seizure of illegal prescription drugs, among other contraband.[108] The ferry system serves coastal communities in Alaska, including several of the communities served by KANA. Such diversion and trafficking of prescription opioid drugs manufactured and distributed by Defendants is a direct and foreseeable consequence of their intentional conduct in inflating the market for their highly addictive drugs across the country, and then flooding that market through the distribution of large quantities of those drugs while ignoring "red flags" and flouting the very laws and regulations designed to prevent unlawful diversion.

D. Defendants' unlawful conduct and breaches of legal duties caused harm and substantial damages to KANA

241. Defendants' actions, including false and misleading advertising and a failure to prevent diversion, have fueled a new wave of addiction and injury throughout the United States. As the Manufacturer Defendants' efforts to expand the market for opioids increased, so have the rates of prescription and sale of their products—and the rates of opioid-related substance abuse, hospitalization, and death among the people of the United States and Alaska. The Distributor Defendants have continued to unlawfully ship massive quantities of these drugs throughout the

[107] Alaska Opioid Policy Taskforce, Final Recommendations, 2017, page 4, *available at* http://dhss.alaska.gov/AKOpioidTaskForce/Documents/AOPTF-Recommendations-1-19-17.pdf.

[108] *See* Liz Thomas, *Marine Highway operation leads to meth, heroin seizures*, KTVA (July 6, 2018), *available at* http://www.ktva.com/story/38590945/marine-highway-operation-leads-to-meth-heroin-seizures.

United States, including Alaska, knowing that a substantial portion were being diverted and feeding the nationwide opioid epidemic.

242. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread overuse, misuse, and diversion of prescription opioids across the Nation, throughout Alaska, and in the geographic area and eligible patient population served by KANA.

243. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[109]

244. For example, reflecting the increase in opioid supply and demand, dosage units of OxyContin and generic oxycodone seized by law enforcement in Alaska increased from 1,183 in 2014 to 4,552 in 2016.[110]

245. Further, because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, such as heroin, the massive distribution of prescription opioids throughout the United States and Alaska has caused an opioid epidemic that includes heroin addiction, abuse, and death. According to the National Institute of Health's National Institute on Drug Abuse, about 80 percent of people who use heroin first misused prescription opioids.[111]

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[109] Richard C. Dart, et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Engl. J. Med. 241 (2015), https://www.nejm.org/doi/full/10.1056/NEJMsa1406143.
[110] *Alaska State Troopers Annual Drug Report*, *supra* note 106, at 13.
[111] *See* National Institute on Drug Abuse, NIH, *Opioid Overdose Crisis* (Revised March 2018), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#seven.

246. Many patients presenting to KANA who are abusing opioids, including heroin, first became addicted as the result of a legitimate prescription. When the Kodiak community began to monitor and limit the prescribing of opiates by medical providers in response to the opioid crisis, Jay Butler, the chief medical officer for the Alaska Department of Health and Social Services, noted that this effort resulted in an "opiate hunger," leading addicts to seek heroin.

247. The largest drug bust in Kodiak history took place in 2014, with officials seizing $2.2 million worth of heroin and methamphetamine.[112] In 2016, Kodiak Police seized 127.7 grams Heroin, valued at $76,620.00, and 53 doses of Prescription Pills, valued at $5,000.00.[113]

248. Heroin is one of the primary substances abused by Alaskans, and both prescription opiate abuse and availability of synthetic opioids, such as fentanyl, are on the rise in Alaska. The most recent Alaska State Troopers Annual Drug Report concludes, "The producers of synthetic opioids are essentially piggybacking on the market created from prescription medication diversion as well as increase [in] the volume and profits on heroin." The Report notes at least 122 overdose deaths due to heroin and synthetic opioids in Alaska between January 1, 2014 through September 15, 2016.

249. According to the Kodiak Police Department, "The heroin epidemic has seriously affected Kodiak, like other communities throughout Alaska. It is nearly daily that KPD

[112] Laurel Andrews, Anchorage Daily News (fka Alaska Dispatch New), "Kodiak police seize $2.2 million in meth, heroin" April 21, 2014, *available at* https://www.adn.com/crime-justice/article/kodiak-police-seize-22-million-meth-heroin/2014/04/21/ (Last updated September 28, 2016) (last accessed August 13, 2018).
[113] Alaska State Troopers Annual Drug Report 38 (2016), https://dps.alaska.gov/getmedia/f259530b-5277-408e-9d45-4999958fe530/2016-Annual-Drug-Report-6-28-17final;.aspx.

officers come in to contact with individuals who are in possession of, or high on, heroin."[114] "In 2017, Kodiak saw a substantial increase in heroin overdoses, and the arrival of fentanyl. The social issues caused by drug addiction had a major impact in the community."[115]

250. Among Alaska Natives, there were 52 deaths with underlying or contributing cause listed as opioids between 2014 and 2016.[116]

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[114] Alaska State Troopers Annual Drug Report (2016), https://dps.alaska.gov/getmedia/f259530b-5277-408e-9d45-4999958fe530/2016-Annual-Drug-Report-6-28-17final;.aspx.

[115] Alaska State Troopers Annual Drug Report (2017), https://dps.alaska.gov/getmedia/1c42905b-dc16-453e-aad5-cfc99d9bc425/2017-Annual-Drug-Report-Final-083018

[116] Presentation by Gretchen Day, ANTHC Clinical & Research Services, and Erin Semmens, University of Montana, "Data Indicators of Opioid Use in Alaska and Montana at the American Indian Alaska Native Clinical and Traditional Research Program Opioid Research Symposium, slide 10, March 29, 2018.

Mortality: Alaska Native Deaths (2014-2016)

52 deaths with underlying or contributing cause listed as opioids.

Age Group	Drug	Type	Deaths	Proportion
15-24	Heroin	Illegal Street Drug	8	**67%**
	Opioids	Prescription	2	
	Methadone	Addiction Treatment	1	
	Synthetic	Very dangerous	1	
	Total		12	
25-44	Heroin	Illegal Street Drug	15	**56%**
	Opioids	Prescription	9	**33%**
	Methadone	Addiction Treatment	3	
	Total		27	
45-64	Heroin	Illegal Street Drug	3	
	Opioids	Prescription	8	**67%**
	Methadone	Addiction Treatment	1	
	Total		12	

Figure 1[117]

[117] *Id*. slide 11.

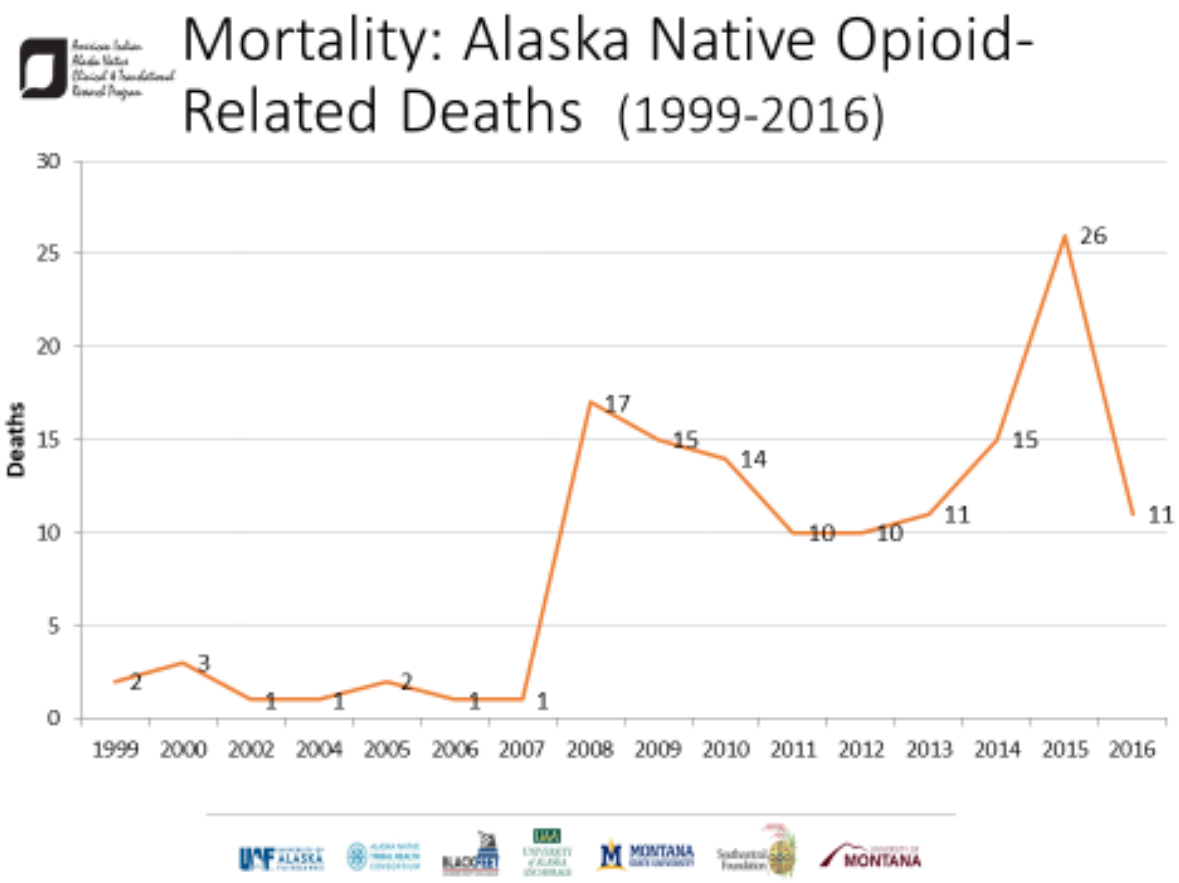

Figure 2[118]

251. Opioid-related deaths represent only the tip of the iceberg. KANA has treated and continues to treat numerous patients with opioid-related conditions, including overdose, addiction, and other related conditions.

252. KANA has seen an increase in opioid use among its service population in recent years. KANA screens all individuals seeking mental health or substance abuse services, and between September of 2014 and September of 2015, 63% of those individuals screened positive for substance abuse problems. Opioids are increasingly the substance of choice for these

[118] *Id*. slide 10.

patients. In FY 2016, opioids were not in the top three substances used by patients admitted to KANA's substance use programs, but in FY17, opioids jumped to # 2, with 26 out of 128 people served in KANA's substance use programs reporting opioids as their substance of choice. In FY18, they are still the second most reported substance of choice (after alcohol): 34 of 132 people served in substance use programs report opioids as their substance of choice.

253. These statistics do not capture the full extent of opioid misuse among KANA's patient population, but they are indicative of the rising toll of the opioid epidemic on this population and the resulting impact to KANA.

254. KANA has incurred a wide range of costs associated with the treatment of these opioid-affected patients. As a result of opioid use, affected individuals require a spectrum of services ranging from health care to substance abuse and mental health counseling to child welfare services, welfare assistance, vocational rehabilitation services and more.

255. KANA recognized that its patients struggle with opioid use disorder, or are at risk due to co-morbid mental health disorders or high-risk substance use patterns, often struggle with coordinating their own entry into care, resulting in early drop-out rates or failure to engage in care at all. With this information, KANA pursued grant funding with the goal of facilitating smooth and efficient entry into mental health and substance abuse care through early and proactive identification of risk factors, our hope was to increase patients' comfort level in seeking substance abuse and behavioral health care.

256. In 2016, KANA implemented a Medication-Assisted Treatment (MAT) program in response to an increase in patients seeking care for opioid use disorder. Also in 2016, KANA added a substance use counselor to focus on MAT assessments and clients, and in 2017,

KANA added a full-time case manager to focus on case management services for substance abuse clients.

257. KANA has also had set aside funding to support travel by patients to inpatient substance abuse treatment facilities when necessary, as inpatient facilities are not available on Kodiak Island.

258. KANA has instituted additional testing measures and moved to a more expensive urine drug test due to the prevalence of opioid misuse and abuse among its patients. KANA is also providing Deterra® Drug Deactivation System pouches to the community, which allow patients to safely dispose of unwanted or expired prescription painkillers at home.

259. In addition to testing and treatment for substance abuse, medical treatment costs associated with the opioid epidemic and incurred by KANA include, but are not limited to: costs for treating Hepatitis C and other infections due to intravenous drug use by addicted patients; increased costs of pregnancy care; costs associated with Neonatal Abstinence Syndrome (including lasting developmental impacts on affected babies); and costs to transport patients to other facilities when necessary, for example, to a facility that can accommodate an opioid-complicated delivery and birth.

260. Because many of KANA's patients are IHS beneficiaries or otherwise exempt from full payment for services, the costs of their medical care are the direct responsibility of KANA (rather than the patient). Further, many of the health care costs incurred by KANA go unreimbursed, either because the patient is not covered by insurance or another third party payor, or because the third party payor does not reimburse the full costs of the provided services and/or because the patient is exempt from cost sharing that would otherwise apply.

261. KANA has also faced increased operational costs in its health care programs and services relating to dealing with "pill seekers"; provider and staff time dealing with patient complaints over the intentional reduction in opioid prescriptions by KANA providers; provider and staff time reviewing charts and performing necessary patient oversight; dealing with phone calls from patients seeking early prescription refills; the need for longer and more frequent appointments; the need to track down patients who are missing appointments; additional testing; additional staff training; and staff turnover due to the stress of treating patients with chronic opioid use disorders, among other things. KANA has also instituted various measures such as an Opioid Review Committee, which was in place for several years, and pain contracts requiring staff hours to implement. KANA has had to address staff safety concerns, as a result of irrational behavior of patients who appear to be under the influence. This includes adding additional staff and schedule changes, at an increased expense to the organization.

262. Further, KANA has expended staff time and other resources to apply for grants to respond to the opioid epidemic in light of the massive funding needs it has created. For example, in 2017, KANA applied for an Indian Health Service grant (Behavioral Health Integration Initiative - BH2I) to expand its existing integrated approach to behavioral health and primary care services utilizing a Behavioral Health Consultant Model. This grant helped fund two Behavioral Health Consultants who will receive warm handoffs, consult with medical providers and/or a psychiatric consultant on patient needs, and implement treatment plans that target immediate Behavioral Health needs or assist with necessary care coordination for chronic, ongoing care needs. KANA recognized the need to hire two additional new positions, who are located within the primary care center to provide immediate intervention.

263. These efforts, and the associated costs, have become necessary in light of the opioid crisis, and they have placed an increasing burden on KANA and its limited resources.

264. As a result, KANA must divert resources away from other health priorities that it is responsible for addressing, like general behavioral health needs, and tobacco and alcohol prevention programs. The National Survey on Drug Use and Health (NSDUH), which looks at Alaskans over 18, the rate of non-medical use of pain relievers in 2013/2014 was between 3.5% and 5.5%, while the heroin use rate in 2015/2016 was between 0.5% and 1.5%. The 2017 Youth Risky Behavior Survey (YRBS) found that Kodiak students reported having abused prescription pain medication at a rate between 8.9% and 14.2%, and a heroin ever-use rate of 3.5% to 8.6%. These numbers are concerning, especially when paired with low risk perception among students about prescription pill abuse (10.8% to 18.7% believe prescription pill abuse has no risk of harm, while up to 34.8% say it has slight or no risk of harm), As a result, KANA's Prevention Team has shifted its work to more heavily emphasize education and outreach on the topic of opioids, with a specific focus on improving understanding of the link between prescription pill and heroin use, as well as the promotion of alternate disposal systems. Further, at least a portion of the diverted funds could have otherwise been used to provide care and services that are reimbursed by third party payors.

265. Opioid diversion also contributes to a range of social problems including physical and mental consequences, crime (including increased domestic violence and sexual assault, requiring medical treatment for the victim), delinquency, loss of employment and/or housing, and child welfare issues.

266. KANA provides a range of social services to its beneficiaries, including family

services (including infant learning, child advocacy, and child welfare services as well as childcare assistance, Temporary Assistance for Needy Families, and WIC); employment and training for adult and youth, including vocational rehabilitation; elder services; public safety (through its Village Public Safety Officer Program); and economic development. Further, KANA operates a Medical-Legal Partnership program that provides free civil legal services to qualifying patients. KANA has incurred increased costs in the provision of these services as a result of the opioid epidemic.

267. The Indian Child Welfare Act (ICWA) was passed in response to the alarmingly high number of Indian children being removed from their homes by both public and private agencies. The intent of Congress under ICWA was to "protect the best interests of Indian children and to promote the stability and security of Indian tribes and families" (25 U.S.C. § 1902). Indian children involved in state child custody proceedings are covered by ICWA, which sets out federal requirements regarding removal and placement of Indian children in foster or adoptive homes and allows the child's tribe to intervene in the case. KANA is involved in these matters through its ICWA/Family Services/Community Health staff. Over time, ICWA cases involving opioid use have increased. In 2013 and 2014, KANA had zero ICWA cases related to opioid use; in 2015: 43% of cases related to opioid use; 2016: 33% of cases related to opioid use; 2017: 75% of cases related to opioid use; 2018: 80%.

268. It was entirely foreseeable that service providers like KANA would need to incur such costs in response to the widespread overuse and misuse of opioids in the geographic area, communities, and patient populations they serve, as precipitated by Defendants' actions alleged herein.

269. Additionally, as health care providers, KANA has purchased and continues to purchase and administer opioids marketed and sold by Defendants, and was and continues to be a recipient of the widespread misinformation campaign by the Manufacturer Defendants alleged in this Complaint. The Defendants have marketed and continue to market their opiate products directly to health care providers throughout the country and Alaska, using various means. KANA thus was and is a direct customer and victim of the Defendants' false, deceptive, widespread and unfair marketing of opioids.

270. As a direct result of Defendants' conduct, KANA and the Communities it serves have suffered actual injury and economic damages including, but not limited to, expenses for first responders (including VPSO's), health care costs, child protection services, transportation of patients and other services and costs, as alleged herein.

271. Defendants' intentional and/or unlawful conduct aimed at increasing sales and distribution of opioids resulted in direct, foreseeable, past and continuing economic damages to KANA, for which KANA now seeks relief.

272. KANA is in need of additional resources to fully abate the opioid crisis in the Communities it serves, including but not limited to: increased access to naloxone; increased training for VPSO's and village health aides; increased funds for enforcement, investigation, education, intervention, or emergency treatment; drug "takeback" sites and programs, drug disposal bags, locally available inpatient treatment and community prevention programming, among other measures.

273. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opioids, Defendants should be required to take

responsibility for the financial burdens their conduct has imposed upon KANA and for the costs of abatement of the crisis.

E. The statutes of limitations are tolled and Defendants are estopped from asserting statutes of limitations as defenses

1. Continuing Conduct

274. Defendants' conduct as described in this Complaint is still ongoing, and KANA continues to suffer harm from the Defendants' unlawful actions.

275. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

2. Equitable Estoppel and Fraudulent Concealment

276. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including KANA, that they were undertaking efforts to comply with their obligations under the controlled substances laws. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public and KANA that they are working to curb the opioid epidemic.

277. The Defendants were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

278. Specifically, as described above, the Manufacturer Defendants deliberately worked through Front Groups purporting to be patient advocacy and professional organizations, through public relations companies hired to work with the Front Groups and through paid KOLs to secretly control messaging, influence prescribing practices, and drive sales. The Manufacturer Defendants concealed their role in shaping, editing, and approving the content of prescribing guidelines, informational brochures, KOL presentations, and other false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers, and the public at large. They manipulated scientific literature and promotional materials to make it appear that misleading statements about the risks, safety, and superiority of opioids were actually accurate, truthful, and supported by substantial scientific evidence. Through their public statements, omissions, marketing, and advertising, the Manufacturer Defendants' deceptions deprived KANA of actual or implied knowledge of facts sufficient to put KANA on notice of potential claims.

279. All Defendants concealed the existence of KANA's claims against them by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways, insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers, and the public (including KANA), and deprived KANA of actual or implied knowledge of the Defendants' role in the opioid epidemic and of facts sufficient to put

them on notice of potential claims against the Defendants.

280. For example, a Cardinal executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[119]

281. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[120]

282. Distributor Defendants, through their trade associations, filed an amicus brief that represented that Defendants took their duties seriously, complied with their statutory and regulatory responsibilities, and monitored suspicious orders using advanced technology.[121]

283. Defendants have also concealed and prevented discovery of information, including data from the ARCOS database that will confirm their identities and the extent of their wrongful and illegal activities.

284. Defendants also lobbied Congress and actively attempted to halt DEA investigations and enforcement actions and to subvert the ability of agencies to regulate their conduct.[122] As a result, there was a sharp drop in enforcement actions and the standard for the DEA to revoke a distributor's license was raised.

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[119] Lenny Bernstein et al., *How drugs intended for patients ended up in the hands of illegal users: "No one was doing their job,"* The Wash. Post (Oct. 22, 2016), *available at* http://wapo.st/2etAUdQ?tid=ss_mail&utm_term=.f455a35fdee5 (last accessed Aug. 13, 2018).

[120] Scott Higham et al., *Drug industry hired dozens of officials from the DEA as the agency tried to curb opioid abuse*, The Wash. Post, Dec. 22, 2016, *available at* http://wapo.st/2hKYW3y?tid=ss_mail&utm_term=.bdac6eb4ec17 (last accessed Aug. 13, 2018).

[121] Brief for Healthcare Distribution Mgmt. Ass'n and Nat'l Ass'n of Chain Drug Stores as *Amici Curiae* in Support of Neither Party, *Masters Pharm, Inc. v. U.S. Drug Enf't Admin*. (No. 15-1335), 2016 WL 1321983, at *3-4, *25. (D.C. Cir. Apr. 4, 2016).

[122] *See* Higham and Bernstein, *supra* note 92.

285. Because the Defendants concealed the facts surrounding the opioid epidemic, KANA did not know of the existence or scope of the Defendants' misconduct, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

286. Defendants knew that their conduct was deceptive, as evidenced by the governmental warnings, actions, and prosecutions alleged throughout this Complaint.

287. Defendants intended that their false and deceptive statements and omissions be relied upon, including by KANA and the communities, tribes and individuals served by KANA. KANA reasonably relied on these statements and omissions.

288. Defendants cannot claim prejudice due to a late filing because this suit was filed upon discovering the facts essential to the claim, which Defendants themselves intentionally concealed. Indeed, the existence, extent, and damage of the opioid crisis have only recently come to light.

289. KANA was unable to obtain vital information regarding these claims absent any fault or lack of diligence on their part.

F. Facts Pertaining to Claims Under RICO

290. Defendants did not simply scheme to market opioids through misrepresentations and turning a blind eye to diversion. Various groups of Defendants also formed informal associations with others (Enterprises) and used these Enterprises to perpetrate their schemes, as described below. KANA also realleges all preceding paragraphs of this Complaint, which are incorporated herein in their entirety.

1. The Opioid Marketing Enterprise

a. The Common Purpose and Scheme of the Opioid Marketing Enterprise

291. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the Manufacturing Defendants formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

292. In order to unlawfully increase the demand for opioids, the Manufacturing Defendants formed an association-in-fact enterprise (the "Opioid Marketing Enterprise") with the Front Groups and KOLs described above. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose. The Manufacturing Defendants' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioid-friendly messaging, fueled the U.S. opioid epidemic.

293. The Manufacturing Defendants, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including KANA and the people it serves, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included the following: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the Manufacturer Defendants named "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids

improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

294. The misleading statements not only caused and worsened the opioid epidemic, but as time went on, they concealed the Manufacturer Defendants' wrongdoing from the public and KANA (including as a result of the Opioid Marketing Enterprise).

295. The scheme devised, implemented, and conducted by the Manufacturer Defendants constituted a common course of conduct designed to ensure that the Manufacturer Defendants unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effectiveness of their drugs. The Manufacturer Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetrated the Opioid Marketing Enterprise's scheme, including through the unbranded promotion and marketing network as described above.

296. There was regular communication among the Manufacturer Defendants, Front Groups, and KOLs, in which information was shared, misrepresentations were coordinated, and payments were exchanged. Typically, the coordination, communication, and payment occurred, and continues to occur, through the repeated and continuing use of interstate wires and mail in which the Manufacturer Defendants, Front Groups, and KOLs shared information regarding overcoming objections and resistance to the use of opioids for chronic pain. The Manufacturer Defendants, Front Groups, and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence. These

actions were effective to conceal the scheme and the Opioid Marketing Enterprise and its impact from KANA until sufficient information came to light due to government and media investigation to allow KANA to discover it, leading to the filing of the Complaint in this matter.

297. At all relevant times, the Front Groups were aware of the Manufacturer Defendants' conduct and were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and KANA. But for the Opioid Marketing Enterprise's scheme, the Front Groups would have had incentive to disclose the deceit by the Manufacturer Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, continued its wrongful concealment from KANA, and reaped substantial benefits.

298. At all relevant times, the KOLs were aware of the Manufacturer Defendants' conduct and were knowing and willing participants in and beneficiaries of that conduct. The Manufacturer Defendants selected KOLs because they favored the aggressive treatment of chronic pain with opioids. The Manufacturer Defendants' support helped the KOLs become respected industry experts. As they rose to prominence, the KOLs falsely promoted the benefits of using opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and KANA. But for the Opioid Marketing Enterprise's scheme, the KOLs would have had incentive to disclose the deceit by the Manufacturer Defendants and the Opioid Marketing Enterprise, and

to protect their patients and the patients of other physicians. By failing to disclose this information, the KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose, continued its wrongful concealment from KANA, and reaped substantial benefits.

299. As public scrutiny and media coverage focused on how opioids ravaged communities throughout the United States, the Front Groups and KOLs did not challenge the Manufacturer Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and that the use of opioids for chronic pain was not supported by medically acceptable evidence. The Manufacturer Defendants and their co-conspirators thus continued to conceal the Manufacturer Defendants' wrongdoing from KANA.

b. The Conduct of the Opioid Marketing Enterprise

300. The Manufacturer Defendants, Front Groups, and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. The conduct of the members of the Opioid Marketing Enterprise in furtherance of the Enterprise's common purpose involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term, chronic pain (described in detail above); (2) efforts to criticize or undermine the 2016 CDC Guideline referenced above; and (3) efforts to limit prescriber accountability.

301. In addition to disseminating misrepresentations about the risks and benefits of opioids, members of the Opioid Marketing Enterprise also furthered its common purpose by criticizing or undermining the CDC Guideline, which represented "an important step—and

perhaps the first major step from the federal government—toward limiting opioid prescriptions for chronic pain."[123]

302. Several Front Groups, including the U.S. Pain Foundation and the American Academy of Pain Medicine (AAPM), criticized the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines."[124]

303. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."[125]

304. The Manufacturer Defendants alone could not have accomplished the purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than the Manufacturer Defendants themselves. Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the Opioid Marketing Enterprise could not have achieved its common purpose.

305. In short, the Manufacturer Defendants, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the

[123] Fueling an Epidemic, *supra* note 29, at 13.
[124] Pat Anson, *Chronic Pain Groups Blast CDC for Opioid Guidelines*, Pain News Network, Sept. 22, 2015, https://www.painnewsnetwork.org/stories/2015/9/22/chronic-pain-groups-blast-cdc-for-opioid-guidelines (last accessed August 13, 2018).
[125] Am. Acad. of Pain Medicine, CDC Guideline for Prescribing Opioids for Chronic Pain (Mar. 16, 2016), http://www.painmed.org/files/aapm-statement-cdc-guideline-for-prescribing-opioids-for-chronic-pain.pdf (last accessed August 3, 2018).

Enterprise's purpose.

306. Moreover, each of the Manufacturer Defendants exerted control over the Opioid Marketing Enterprise and participated in the operation or management of its affairs, directly or indirectly. From approximately the late 1990s to the present, that participation and control was carried out in the following ways:

a. Creating and providing a body of deceptive, misleading, and unsupported medical and popular literature, electronic and print advertisements, sales and promotional training materials, and presentations about opioids that: (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) were thus more likely to be relied upon by physicians, patients, and payors;

b. Selecting, cultivating, promoting, and paying Front Groups and KOLs based on their willingness to communicate and distribute the Manufacturer Defendants' messages about the use of opioids for chronic pain;

c. Providing substantial opportunities for Front Groups and KOLs to participate in research studies on topics the Manufacturer Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

d. Paying KOLs to serve as consultants or on the Manufacturer Defendants' advisory boards, or on the advisory boards and in leadership positions of Front Groups, and to give talks, typically over meals or at conferences;

e. Paying significant amounts of money to the leaders and individuals

associated with Front Groups;

f. Donating to Front Groups to support talks that were typically presented over meals or at conferences;

g. Disseminating false, misleading, imbalanced, and unsupported statements regarding opioids through unbranded materials that appeared to be independent publications from Front Groups;

h. Sponsoring programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

i. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and Front Groups as publishers and supporters;

j. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the Manufacturer Defendants, such as veterans and the elderly, and then funding that distribution;

k. Concealing their relationship to and control of Front Groups and KOLs from KANA and the public at large; and

l. Intending that Front Groups and KOLs would distribute, through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

307. In short, the Manufacturer Defendants controlled representations made about their prescription opioids, doled out funds to Pharmacy Benefit Managers and payments to KOLs, and ensured that representations made by KOLs, Front Groups, and the Manufacturer

Defendants' sales detailers were consistent with the Manufacturer Defendants' messaging throughout the United States. The Front Groups and KOLs in the Opioid Marketing Enterprise were dependent on the Manufacturer Defendants for their financial structure and for career development and promotion opportunities.

308. The Front Groups also conducted and participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding opioids and the Manufacturer Defendants' drugs that were consistent with the Manufacturer Defendants' messages;

b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials that claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain;

c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the Manufacturer Defendants;

d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The Front Groups strongly criticized the 2016 CDC Guideline, which had recommended limits on opioid prescriptions for chronic pain; and

f. The Front Groups concealed their connections to the KOLs and the Manufacturer Defendants.

309. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding opioids and the Manufacturer Defendants' drugs that were consistent with the Manufacturer Defendants' messages;

b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials that claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain;

c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the Manufacturer Defendants;

d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The KOLs strongly criticized the 2016 CDC Guideline, which had recommended limits on opioid prescriptions for chronic pain; and

f. The KOLs concealed their connections to the Front Groups and the Manufacturer Defendants, and their sponsorship by the Manufacturer Defendants.

310. The scheme devised and implemented by the Manufacturer Defendants and members of the Opioid Marketing Enterprise amounted to a common course of conduct intended to increase the Manufacturer Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term, chronic pain. The scheme was a continuing course

of conduct, and many aspects of it continue to the present.

311. The Manufacturer Defendants, Front Groups and the KOLs thus worked together to promote the goals of the Opioid Marketing Enterprise.

c. The Pattern of Racketeering Activity

312. The Manufacturer Defendants' scheme was perpetrated through multiple acts of mail fraud and wire fraud that constituted a pattern of racketeering activity.

313. This pattern of racketeering activity involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities, including misrepresentations, concealments, and material omissions regarding the beneficial uses and non-addictive qualities of prescription opioids for the long-term treatment of chronic, non-acute, and non-cancer pain, with the goal of profiting from increased sales of the Manufacturer Defendants' opioids.

314. Each of these fraudulent mailings and interstate wire transmissions constitutes a separate act of racketeering activity, and collectively, these violations constitute a pattern of racketeering activity.

315. The Manufacturer Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive, and effective use of opioids for long-term, chronic, non-acute, and non-cancer pain. The Manufacturer Defendants and members of the Opioid Marketing Enterprise knew that these representations violated the FDA-approved use of these drugs, and were not supported by actual evidence. The Manufacturer Defendants used the U.S. Mail and interstate wire facilities, intentionally and knowingly, with the specific intent to defraud and to advance their illegal

scheme.

316. The Manufacturer Defendants, the Front Groups, and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity by intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers, regulators, the public, and KANA.

317. The Manufacturer Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the fraudulent marketing of opioids involved thousands of communications, publications, representations, statements, electronic transmissions, and payments, including, *inter alia*:

a. Marketing materials about opioids and their risks and benefits, which Manufacturer Defendants, Front Groups, and KOLs published and transmitted to healthcare providers located across the country through the Internet and television;

b. Written representations and telephone calls between the Manufacturer Defendants and Front Groups regarding the misrepresentations, marketing statements, and claims about opioids, including the non-addictive, safe use of prescription opioids for chronic long-term pain generally;

c. Written representations and telephone calls between the Manufacturer Defendants and KOLs regarding the misrepresentations, marketing statements, and claims about opioids, including the non-addictive, safe use of prescription opioids for chronic long-term pain generally;

d. E-mails, telephone calls, and written communications between the

Manufacturer Defendants and the Front Groups agreeing to or implementing the scheme for the fraudulent marketing of opioids;

e. E-mails, telephone calls, and written communications between the Manufacturer Defendants and the KOLs agreeing to or implementing the scheme for the fraudulent marketing of opioids;

f. Communications between the Manufacturer Defendants, Front Groups, and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

g. Communications between the Manufacturer Defendants, KOLs, and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

h. Written and oral communications directed to state agencies, Federal and state courts, and private insurers throughout the country that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

i. Receipts of increased profits—the wrongful proceeds of the scheme—sent through the U.S. Mail and interstate wire facilities.

318. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the Manufacturer Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

319. The Manufacturer Defendants, and each member of the Opioid Marketing Enterprise, agreed, with knowledge and intent, to the overall objective of the Manufacturer

Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud in marketing prescription opioids.

320. Indeed, for the Manufacturer Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the Manufacturer Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, presentations, and prescription guidelines.

321. The Manufacturer Defendants' predicate acts all had the purpose of creating the opioid epidemic that substantially injured KANA's business and property, while simultaneously generating billion-dollar revenues and profits for the Manufacturer Defendants. The predicate acts were committed or caused to be committed by the Manufacturer Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

2. The Opioid Supply Chain Enterprise

a. The Common Purpose and Scheme of the Opioid Supply Chain Enterprise

322. In addition to the Opioid Marketing Enterprise, there existed a second, separate enterprise. For more than a decade, all Defendants worked together in an illicit enterprise, engaging in illegal conduct with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict (the "Opioid Supply Chain Enterprise").

323. As "registrants" under the CSA, Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of

unusual frequency." Critically, Defendants' responsibilities do not end with the products they manufacture or distribute—there is no such limitation in the law because their duties cut across company lines. Thus, when Defendants obtain information about the sales and distribution of other companies' prescription opioid products (including both name-brand prescription opioids and their generic equivalents), they were legally obligated to report that activity to the DEA. On information and belief, the Defendants did in fact obtain such data through data mining companies.

324. Defendants breached their duties under the CSA. Through the connections they made as a result of their participation in the HDA, Defendants chose to flout the closed system designed to protect citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention of Diversion of Controlled Substances." But, privately, Defendants refused to act. Indeed, despite the issuance of these Industry Compliance Guidelines (which recognize Defendants' duties under the law), none of them complied. This noncompliance is illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time.

325. Further, John Gray, President and CEO of the HDA, said to Congress in 2014, it is "difficult to find the balance between proactive and anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications."[126] Yet, Defendants apparently all found the same profit-maximizing balance and intentionally remained silent to ensure the largest possible financial return.

326. Defendants breached their duties under the CSA, and the breaches were part

[126] *Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 113th Cong. (2014) (statement of John Gray, President and CEO, HDA), https://www.gpo.gov/fdsys/pkg/CHRG-113hhrg90872/html/CHRG-113hhrg90872.htm.

of a common purpose and scheme. At all relevant times, Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by fraudulently increasing the quotas set by the DEA that would allow them to benefit collectively from a greater pool of prescription opioids. In support of this common purpose and fraudulent scheme, Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market. Their collective silence in the face of their duties to speak constituted concealment of their wrongdoing that effectively kept it hidden from the public and KANA until government and media investigation revealed sufficient information to bring their wrongful conduct causing the opioid epidemic to light, leading to the Complaint in this matter.

b. The Conduct of the Opioid Supply Chain Enterprise

327. At all relevant times, Defendants exerted control over, conducted, and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties to identify, investigate, and report suspicious orders of opioids.

328. Defendants disseminated false and misleading statements to Federal and state regulators claiming that:

a. the quotas for prescription opioids should be increased; and

b. they were complying with their obligations to: (i) maintain effective controls against diversion of their prescription opioids; (ii) design and operate a system to disclose suspicious orders of prescription opioids; and (iii) notify the DEA of any suspicious orders or diversion of their prescription opioids.

329. The CSA and the Code of Federal Regulations require Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute. It also constitutes concealment of Defendants' wrongful fulfillment of suspicious orders.

330. Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records, and other documents required to be filed with the DEA, including the Manufacturer Defendants' applications for production quotas. Specifically, Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

c. The Pattern of Racketeering Activity

331. Defendants used, directed the use of, and/or caused to be used, thousands of mail and interstate wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

332. Defendants devised and knowingly carried out a scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts when there was a duty to disclose.

333. For the purpose of executing the illegal scheme, Defendants used the mail and interstate wires intentionally and knowingly with the specific intent to defraud and advance the illegal scheme. These repeated acts of mail fraud and wire fraud constituted a pattern of racketeering activities.

334. Defendants' use of the mail and interstate wires included, but was not limited to, the transmission, delivery, or shipment of the following by Defendants, or third parties that foreseeably sent them as a result of Defendants' illegal scheme:

a. The prescription opioids themselves;

b. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

c. Documents and communications that facilitated the manufacture, purchase, and sale of prescription opioids;

d. Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated Defendants' DEA registrations;

f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of the

Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports, and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributor Defendants to the Manufacturer Defendants;

k. Rebates and chargebacks from the Manufacturer Defendants to the Distributor Defendants;

l. Payments to the Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

m. Deposits of proceeds from the Defendants' manufacture, distribution, and sale of prescription opioids; and

n. Other documents and things, including electronic communications.

335. Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents affecting interstate commerce.

336. Defendants used the Internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Defendants made misrepresentations about their compliance with Federal and state laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

337. At the same time, Defendants misrepresented the superior safety features of

their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all Federal and state regulations regarding the identification and reporting of suspicious orders of prescription opioids.

338. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators, the public, and KANA into believing that Defendants were complying with their Federal and state obligations to identify and report suspicious orders of prescription opioids while Defendants were knowingly allowing millions of doses of prescription opioids to be diverted into the illicit drug market. Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

339. Many of the precise dates of the uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, KANA has described the types of and, in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetrate and maintain the scheme, including the things and documents described in the preceding paragraphs.

340. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

341. The predicate acts all had the purpose of creating the opioid epidemic that

substantially injured KANA's business and property, as well as the health and welfare of the communities and individuals served by KANA, while simultaneously generating billion-dollar revenue and profits for Defendants. The predicate acts were committed or caused to be committed by Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

342. As described above, Defendants were repeatedly warned, fined, and found to be in violation of applicable laws and regulations, and yet they persisted. The sheer volume of enforcement actions against Defendants supports this conclusion that Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.[127]

343. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

3. Effects of the Opioid Marketing Enterprise and the Opioid Supply Chain Enterprise

344. KANA's injuries were proximately caused by Defendants' racketeering activity. The racketeering activity was undertaken with the express purpose of influencing the medical community of which KANA is a part, and/or of profiting from such influence, and it directly caused the over-prescription, over-purchase, and over-consumption of name-brand prescription opioids and their generic equivalents. But for Defendants' misstatements and omissions and the schemes employed by the Opioid Marketing Enterprise and the Opioid Supply

[127] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

Chain Enterprise, KANA would not be bearing the costs of the current opioid epidemic.

345. By reason of, and as a result of the conduct of each of the Defendants, and in particular, their pattern of racketeering activity, KANA has been injured in their business and property in multiple ways, including, but not limited to, increased program and operational costs.

346. Defendants' violations of 18 U.S.C. § 1962(c) have directly and proximately caused injuries and damages to KANA, and KANA is entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

V. CAUSES OF ACTION

COUNT 1: VIOLATION OF RICO
18 U.S.C. § 1961 *et seq*.
OPIOID MARKETING ENTERPRISE
(Against Manufacturing Defendants)

347. KANA incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

348. At all relevant times, the Manufacturer Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

349. The Opioid Marketing Enterprise was an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4) consisting of the Manufacturer Defendants, the Front Groups, and the KOLs. The activities of this Enterprise affected interstate commerce.

350. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each member of the Opioid Marketing Enterprise; (b) was separate

and distinct from the pattern of racketeering in which the Manufacturer Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the Manufacturer Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the Manufacturer Defendants and each of the Front Groups and KOLs; (e) had sufficient longevity for the Opioid Marketing Enterprise to pursue its purpose; and (f) functioned as a continuing unit.

351. In particular, each of the Manufacturer Defendants, KOLs, and Front Groups that made up the Opioid Marketing Enterprise had systematic links to, and personal relationships with, each other through: (a) joint participation in lobbying groups; (b) trade industry organizations; (c) contractual relationships; and (d) continuing coordination of activities. These systematic links and personal relationships allowed members of the Opioid Marketing Enterprise to act with a common purpose and to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of the Manufacturer Defendants coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry-friendly and would work together with the Manufacturer Defendants to advance the common purpose of the Opioid Marketing Enterprise.

352. Each of the Manufacturer Defendants and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a role in furthering the Enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading

information about the safety and efficacy of long-term opioid use.

353. Specifically, the Manufacturer Defendants: (1) through the use of Front Groups that appeared to be independent of the Manufacturer Defendants; (2) through the dissemination of publications that supported the Manufacturer Defendants' scheme; (3) through continuing medical education (CME) programs controlled and/or funded by the Manufacturer Defendants; (4) by the hiring and deployment of so-called KOLs who were paid by the Manufacturer Defendants to promote their message; and (5) through the "detailing" activities of the Manufacturer Defendants' sales forces, conducted an association-in-fact enterprise, and/or participated in the conduct of that enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry out the common purpose of the Opioid Marketing Enterprise.

354. The Opioid Marketing Enterprise sought to further this common purpose through a fraudulent scheme to change prevailing views and prescribing habits within the medical community, as well as public perception about the safety and efficacy of opioid use. In so doing, each of the Manufacturer Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise by engaging in mail and wire fraud in violation of 18 U.S.C. § 1962(c).

355. Together with the Front Groups and KOLs, the Manufacturer Defendants formed an association-in-fact enterprise, the Opioid Marketing Enterprise, for the purpose of increasing unlawful profits and revenues from the continued prescription and use of name-brand prescription opioids and their generic equivalents for long-term, chronic pain and through creating widespread dependency on, and addiction to, opioids.

356. The Manufacturer Defendants each worked together to coordinate the Opioid Marketing Enterprise's goals and conceal their role, and the Opioid Marketing Enterprise's existence, from the medical community and the public by, among other things: (a) funding, editing, and distributing publications that supported and advanced their false messages; (b) funding KOLs to promote their false messages; (c) funding, editing, and distributing CME programs to advance their false messages; and (d) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists (that is, sales detailing).

357. Each of the Front Groups helped disguise the role of the Manufacturer Defendants by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials—a body of biased and unsupported scientific "literature," and "treatment guidelines" that promoted the Manufacturer Defendants' false messages.

358. Each of the KOLs was a physician chosen and paid by one or more of the Manufacturer Defendants to influence prescribers' habits by promoting the Manufacturer Defendants' false messages through, among other things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring the Manufacturer Defendants' role in the Opioid Marketing Enterprise and the Opioid Marketing Enterprise's existence.

359. The Manufacturer Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(5) that employed the use of mail and interstate wire facilities, in violation

of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing medical thinking, prescriber habits, and public perceptions in order to increase the prescription and use of prescription opioids.

360. The Manufacturer Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud.

361. Indeed, for the Manufacturer Defendants' fraudulent scheme to work, each of the Manufacturer Defendants had to agree to implement similar tactics.

362. The Manufacturer Defendants' predicate acts of racketeering activity (18 U.S.C. § 1961(1)) consisted of:

a. Mail Fraud: The Manufacturer Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

b. Wire Fraud: The Manufacturer Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by interstate wires for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

363. Each of the Manufacturer Defendants not only violated the above laws but

also aided and abetted others in the violation of the above laws, thereby rendering the Manufacturer Defendants indictable as principals.

364. As summarized herein, the Manufacturer Defendants used the mail and interstate wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions, and payments to carry out the Opioid Marketing Enterprise's fraudulent scheme.

365. Because the Manufacturer Defendants disguised their participation in the Opioid Marketing Enterprise, and worked to keep even the Opioid Marketing Enterprise's existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the Manufacturer Defendants, Front Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise depended upon secrecy. However, KANA has described occasions on which the Manufacturer Defendants, Front Groups, and KOLs disseminated misrepresentations and false statements to prescribers, consumers, and regulators, and how those acts were in furtherance of the scheme.

366. The Manufacturer Defendants each committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the Manufacturer Defendants committed, conspired to commit, and/or aided and abetted in the commission of, were related to each other, posed a threat of continued

racketeering activity and/or constituted continuous racketeering activity, and therefore constituted a "pattern of racketeering activity." The racketeering activity was made possible by the Manufacturer Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise. The Manufacturer Defendants participated in the scheme to defraud by using mail and interstate wires (including telephones and the Internet) in interstate or foreign commerce.

367. As described herein, the Manufacturer Defendants engaged in a pattern of related and continuous acts for years. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers, prescribers, regulators, and KANA.

368. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs.

369. The Manufacturer Defendants, Front Groups, and KOLs intentionally crafted their fraudulent scheme in accordance with the common purpose of the Opioid Marketing Enterprise to ensure that their own profits—and the rewards of the scheme meted out to the Front Groups and KOLs—remained high. In designing and implementing the scheme, the Manufacturer Defendants understood and intended that those in the medical community and the pharmaceutical distribution chain would rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the Manufacturer Defendants' products.

370. The racketeering activities conducted by the Manufacturer Defendants, Front Groups, and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive the medical community, prescribers, consumers, and regulators. The Manufacturer Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing affairs of the Opioid Marketing Enterprise.

371. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

372. The Manufacturer Defendants' violations of law and their pattern of racketeering activity directly and proximately caused KANA injury to its business and property. The Manufacturer Defendants' pattern of racketeering activity was undertaken with the express purpose of influencing the medical community of which KANA is a part, and/or of profiting from such influence, and it logically, substantially, and foreseeably caused an opioid epidemic. KANA's injuries in responding to that epidemic were not unexpected, unforeseen, or independent. Rather, as KANA alleges herein, the Manufacturer Defendants knew that the opioids were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. They further knew that widespread use of prescription opioids could lead to widespread opioid addiction and therefore misuse. Nevertheless, the Manufacturer Defendants engaged in a scheme that utilized the mail and interstate wires in order to carry out the Opioid Marketing Enterprise's fraudulent scheme, thereby increasing the market for and sales of their opioid

products.

373. Specifically, the Manufacturer Defendants' creation of, and then participation in, the Opioid Marketing Enterprise through a pattern of racketeering activities to carry out their fraudulent scheme has injured KANA in the form of substantial losses of money and property that logically, directly, and foreseeably arose from the opioid epidemic. KANA's injuries, as alleged throughout this Complaint, are hereby expressly incorporated herein by reference.

374. KANA is the most directly harmed, and there is no other plaintiff better suited to seek a remedy for the economic harms at issue here. Among other things, no other party is responsible for the costs of services provided to non-paying beneficiaries served by KANA's health care and community programs or for the overhead and programmatic costs described in this Complaint.

COUNT 2: VIOLATION OF RICO
18 U.S.C. § 1961 *et seq*.
OPIOID SUPPLY CHAIN ENTERPRISE
(Against All Defendants)

375. KANA incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

376. At all relevant times, the Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

377. The Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States, including but not limited to creating a

market for non-medical use of opioids of epidemic proportions. The Opioid Supply Chain Enterprise was an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4) consisting of the Defendants. The activities of the Opioid Supply Chain Enterprise affected interstate commerce.

378. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each member of the Opioid Supply Chain Enterprise; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Supply Chain Enterprise, i.e., the Defendants; (e) had sufficient longevity for the Opioid Supply Chain Enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the Enterprise through a pattern of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and the resulting sales.

379. Many of the Defendants are members, participants, and/or sponsors of the HDA/HDMA, and have been since at least 2006, and utilized the HDA/HDMA to form the systematic links and interpersonal relationships of the Opioid Supply Chain Enterprise and to assist the Defendants in engaging in the pattern of racketeering activity that gives rise to this Count.

380. The Defendants conducted and participated in the conduct of the Opioid Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(5).

381. The pattern of racketeering activity of the Opioid Supply Chain Enterprise included the use of mail and interstate wire facilities, in furtherance of a scheme to defraud Federal and state regulators, the American public, and KANA in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

382. The pattern of racketeering activity of the Opioid Supply Chain Enterprise also included the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under the laws of the United States.

383. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person knowingly or intentionally to furnish false or fraudulent information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under that subchapter. A violation of 21 U.S.C. § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1). The Defendants violated 21 U.S.C. § 843(a)(4) by knowingly and intentionally furnishing false information in, and omitting material information from, reports, records, and other documents required to be made, kept, and filed under the relevant subchapter of Title 21 of the United States Code.

384. The Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud.

385. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics.

386. In sum, the Defendants' predicate acts of racketeering activity (18 U.S.C.

§ 1961(1)) consisted of:

a. Mail Fraud: The Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

b. Wire Fraud: The Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by interstate wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

c. Controlled Substance Violations: The Defendants who are Distributor Defendants violated 21 U.S.C. § 843 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.

387. Each of the Defendants not only violated the above laws but aided and abetted others in the violation of the above laws, thereby rendering Defendants indictable as principals.

388. Many of the precise dates of the Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

389. The Defendants hid from the general public and suppressed and/or ignored

warnings from third parties, whistleblowers, and governmental entities about the reality of the suspicious orders that the Defendants were filling on a daily basis—leading to the diversion of hundreds of millions of doses of name-brand and generic prescription opioids into the illicit market.

390. The Defendants committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity within the past ten years.

391. The multiple acts of racketeering activity that the Defendants committed, conspired to commit, and/or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity and/or constituted continuous racketeering activity, and therefore constituted a "pattern of racketeering activity." The racketeering activity was made possible by the Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise.

392. As described herein, the Defendants engaged in a pattern of related and continuous predicate acts for years. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers, prescribers, regulators, and KANA. The predicate acts consisted of a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the distribution and sale of their highly addictive and dangerous drugs. The predicate acts were not isolated or sporadic events.

393. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured KANA's business and property, as well as the health and welfare of the

people served by KANA, while simultaneously generating billion-dollar revenue and profits for the Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

394. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

395. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

396. It was foreseeable to the Defendants that health care and community service providers like KANA would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of name-brand and generic prescription opioids out of appropriate medical channels and into the illicit drug market—causing the opioid epidemic that the CSA intended to prevent.

397. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

398. The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused KANA injury to its business and property. The Defendants' pattern of racketeering activity, including their refusal to identify, report, and halt suspicious orders of controlled substances, logically, substantially, and foreseeably caused an opioid

epidemic. KANA was injured and continue to be injured by the Defendants' pattern of racketeering activity and the opioid epidemic that it created.

399. Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, in order to increase sales of their opioid products, the Defendants engaged in a scheme of deception by refusing to identify or report suspicious orders of prescription opioids that they knew were actually being diverted into the market of non-medical use. They did so by utilizing the mail and interstate wires as part of their fraud.

400. The Defendants' predicate acts and pattern of racketeering activity were a proximate cause of the opioid epidemic that has injured KANA in the form of substantial losses of money and property that logically, directly, and foreseeably arise from the opioid epidemic brought on by the Defendants' acts.

401. Specifically, the predicate acts and pattern of racketeering activity proximately caused KANA's injuries, as alleged throughout this Complaint, and such allegations are expressly incorporated herein by reference.

402. KANA is the most directly harmed, and there is no other plaintiff better suited to seek a remedy for the economic harms at issue here. Among other things, no other party is responsible for the costs of services provided to non-paying beneficiaries served by KANA's health care and community programs or for the overhead and programmatic costs described in this Complaint.

COUNT 3: PUBLIC NUISANCE
(Against All Defendants)

403. KANA incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

404. Public nuisance is an unreasonable interference with a right common to the general public, such as a condition dangerous to health, offensive to community moral standards, or unlawfully obstructing the public in the free use of public property.

405. Defendants' conduct, as described in the Complaint, involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, and unreasonably interferes with a public right.

406. Manufacturer Defendants knew and should have known that their promotion of opioids was false and misleading and that their deceptive marketing practices and other unlawful, unfair, and fraudulent actions would create or assist in the creation of a public nuisance.

407. Distributor Defendants likewise knew and should have known that their failure to use reasonable care or comply with statutory requirements in the distribution of prescription opioids, including the failure to implement effective controls and procedures in their supply chains to guard against theft, diversion, and misuse of controlled substances and to adequately design and implement a system to detect, halt, and report suspicious orders, would create or assist in the creation of a public nuisance.

408. By these actions, all Defendants have created or assisted in the creation of a condition that is injurious to public health and safety and offensive to community moral standards throughout the State of Alaska and within the geographic area and patient population served by

KANA. That nuisance is the over-saturation of opioids, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use, including injury, addiction, and death.

409. The Defendants' actions in creating or assisting in the creation of this nuisance were a legal cause of significant harm to KANA that is different in kind, and not just degree, from the harm to the general public. KANA is responsible for the provision of health care and other social and community services to Alaska Natives, American Indians, and other eligible individuals in the geographic area it serves pursuant to agreements with the federal government under the ISDEAA and other federal laws, as authorized by the federally recognized Alaska Native tribes it serves and represents. The provision of these services is in furtherance of the unique federal trust responsibility to Alaska Natives and American Indians. The resources available to KANA to carry out this responsibility have been and are being unreasonably consumed, as described above, in efforts to address the opioid epidemic, costing KANA considerable sums of money; diverting available resources needed for other services and activities that are part of the federal trust responsibility; and frustrating KANA's ability to meet its responsibilities and carry out its mission.

410. The public nuisance is substantial and unreasonable. Defendants' actions caused and continue to cause the public health epidemic and state of emergency described in this Complaint, and that harm outweighs any offsetting benefit.

411. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used, in deceiving prescribers and patients about the risks and benefits of opioids for the treatment of chronic pain, in the diversion of prescription opioids

for illicit purposes, and in the public health crisis that followed and has reached a state of emergency.

412. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated, and further recurrence of such harm can be abated.

413. KANA has been, and continues to be, injured by Defendants' actions in creating a public nuisance. As a direct and proximate result of the nuisance, KANA has sustained economic harm by spending a substantial amount of money trying to fix the societal harms caused by Defendants' nuisance-causing activity, including, but not limited to, costs of health care, child services, social services, public assistance, and public safety.

414. Defendants should be required to pay the expenses KANA has incurred or will incur in the future to fully abate the nuisance.

COUNT 4: NEGLIGENCE AND GROSS NEGLIGENCE
(Against All Defendants)

415. KANA incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

416. Each Defendant owed and owes a non-delegable duty of care to KANA, including, but not limited to, the duty to exercise due care in the advertising, marketing, promotion, sale and distribution of dangerous opioid drugs; the duty not to make false, misleading, or deceptive statements about opioids; and the duty to take reasonable steps to prevent diversion, misuse, and abuse of prescription opioid drugs.

417. Defendants knew, or should have known, that they breached the duties described above.

418. As set forth above, Defendants' negligent acts include falsely claiming that the risk of opioid addiction was low; falsely instructing doctors and patients that prescribing more opioids was appropriate when patients presented symptoms of addiction; falsely claiming that risk-mitigation strategies could safely address concerns about addiction; falsely claiming that doctors and patients could increase opioid usage indefinitely without added risk; deceptively marketing that purported abuse-deterrent technology could curb misuse and addiction; falsely claiming that long-term opioid use could actually restore function and improve a patient's quality of life; and consciously oversupplying the market for opioids in the State of Alaska and the geographic areas served by KANA. These actions were intended to, and foreseeably did, inflate the market for opioids in Alaska and the geographic area served by KANA.

419. In addition, each Defendant knew or should have known, and/or recklessly disregarded, that the opioids they manufactured, promoted, and/or distributed were being used for unintended uses.

420. For instance, Defendants failed to exercise slight care to KANA by, inter alia, failing to take appropriate action to stop opioids from being used for unintended purposes, including the failure to report suspicious orders or refuse to fill them or otherwise to provide effective controls and procedures to guard against theft and diversion. Furthermore, despite each Defendant's actual or constructive knowledge of the wide proliferation and dissemination of opioids in Alaska and the geographic areas served by KANA, Defendants took no action to prevent the abuse and diversion of their pharmaceutical drugs.

421. Defendants knew or should have known, and/or recklessly disregarded, the fact that KANA, as a health care and community services provider, would be forced to incur

costs and divert resources to treat opioid-affected patients and otherwise respond to the opioid epidemic brought about by Defendants' actions, including the cost of unreimbursed care, increased costs of services, increased overhead costs, and increased public safety costs, among others as alleged throughout this Complaint.

422. But for Defendants' actions, opioid use would not have become so widespread, including within the geographic area and among the population served by KANA, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

423. As a direct and proximate cause of Defendants' unreasonable and negligent conduct, KANA has suffered and will continue to suffer harm, and are entitled to damages in an amount determined at trial.

COUNT 5: NEGLIGENCE PER SE
(Against All Defendants)

424. KANA incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

425. All Defendants were obligated to prevent the diversion of prescription opioids under the CSA and its implementing regulations.

426. The CSA and its implementing regulations were enacted to promote safety and to prevent exactly the type of harm that occurred as a result of Defendants' failures.

427. For negligence *per se*, the court may adopt as the standard of conduct the requirements of a legislative enactment or administrative regulation when the purpose of that legislation or regulation is found to be exclusively or in part: (a) to protect a class of persons which includes the one whose interest is invaded; (b) to protect the particular interest which is

being invaded; (c) to protect that interest against the kind of harm which has resulted; and (d) to protect that interest against the particular hazard from which the harm results. *Estate of Logusak ex rel. Logusak v. City of Togiak*, 185 P.3d 103, 107 (Alaska 2008). As long as the legislative enactment is "not too obscure, outdated or irrational to operate as a standard of reasonable care, the court will instruct the jury that violation of a statute establishes negligence *per se*." *Sinclair v. Okata*, 874 F. Supp. 1051, 1062 (D. Alaska 1994).

428. KANA belongs to the class of persons that the statute was designed to protect, because the CSA was designed to protect the public from the harms that may be caused by the diversion of dangerous drugs from legal to illegal channels and uses. KANA has suffered harms, as detailed above, of the sort contemplated by the CSA because of Defendants' failures, among other things, to prevent the diversion of opioids.

429. Defendants' conduct was negligent *per se* in that Defendants failed to perform their statutory and regulatory obligations under the CSA.

430. Defendants' breaches of their duty of care foreseeably and proximately caused damage to KANA, as alleged above.

431. KANA is entitled to damages from Defendants in an amount to be determined in this litigation.

COUNT 6: UNJUST ENRICHMENT
(Against All Defendants)

432. KANA incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

433. Defendants have unjustly retained a benefit KANA's detriment, and Defendants' retention of that benefit violates the fundamental principles of justice, equity, and

good conscience.

434. KANA has expended substantial amounts of money to address, remedy, and/or mitigate the harms caused by Defendants' conduct, including providing unreimbursed health care, increased social services, and otherwise having to manage the crisis of opioid addiction, overdose, injury, and death that Defendants helped create.

435. The expenditures by KANA in providing treatment services to people who use or are affected by opioids have added to Defendants' wealth. These expenditures should have been borne by the Defendants, and instead KANA has helped to sustain Defendants' business.

436. KANA has thus conferred a benefit upon Defendants, by paying for what may be called Defendants' externalities—the costs of the harm caused by Defendants' negligent distribution and sales practices. This includes providing treatment services to people who use or are affected by opioids, as well as the increased costs of social services and public safety attributable to the opioid epidemic. It further includes necessary training and retraining to correct the misinformation that patients, doctors and the general public, including members served by KANA, have received.

437. Defendants were aware they were receiving this obvious benefit.

438. Meanwhile, Defendants made substantial profits while fueling the opioid epidemic in Alaska and the geographic area, communities, and patient population served by KANA.

439. Defendants continue to receive considerable profits from the distribution of controlled substances in Alaska and the geographic area served by KANA.

440. It would be inequitable for Defendants to retain the full benefit or financial

advantage of their wrongdoing without paying for the externalities necessarily borne by KANA. Defendants should be disgorged of money retained by reason of their deceptive and illegal acts.

441. Because the Defendants were unjustly enriched, KANA is entitled to recover from Defendants' prescription opioid profits the amounts KANA spent and will have to spend in the future to address the effects of Defendants' actions.

COUNT 7: CIVIL CONSPIRACY
(Against All Defendants)

442. KANA incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

443. A civil conspiracy claim requires (1) two or more persons (or entities); (2) an object to be accomplished; (3) a meeting of minds on the object or course of action; (4) one or more unlawful, overt acts; and (5) damages as the proximate result. *Hensel v. Allstate Ins. Co.*, 2007 WL 5613094; *see* 16 Am.Jur. 2d Conspiracy § 51.

444. The Defendants engaged in a civil conspiracy by agreeing to participate in a campaign to accomplish the goals of flooding the market with false and misleading information about the safety of prescription opioid use for the treatment of chronic pain, evading controls on opioid diversion, and increasing opioid quotas.

445. The Defendants did so in an effort to profit off the increased sales of prescription opioids.

446. Each Defendant took one or more unlawful, overt act, including making false or misleading statements directly and through third parties to further the objectives of their conspiracy. These overt acts, as further described above, include but are not limited to acts of mail fraud and wire fraud in furtherance of the Enterprises, and violations of the CSA.

447. KANA was directly and proximately harmed by the Defendants' civil conspiracy, as alleged in this Complaint, in an amount to be determined in this litigation.

COUNT 8: FRAUD AND NEGLIGENT MISREPRESENTATION
(Against Manufacturer Defendants)

448. KANA incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

449. Manufacturer Defendants made fraudulent and/or negligent misrepresentations and omissions of material fact about the use of opioids as part of a widespread misinformation campaign, as more fully described in Paragraphs 140 to 183 and throughout Complaint, which are specifically incorporated here by reference. These misrepresentations and omissions include:

a. Defendant Purdue, with assistance from Defendant Abbott from 1996 through 2002, made and/or disseminated deceptive statements, including, but not limited to, the following: (a) advertising that opioids improved long-term functioning and were suitable for the treatment of chronic non-cancer pain; (b) promoting the concept of pseudo-addiction; (c) brochures concerning indicators of possible opioid abuse; (d) suitability of opioids for high-risk patients; (e) publications presenting an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (f) concealment of funding of pro-opioid KOL doctors regarding treatment for chronic non-cancer pain; (g) downplaying of the risks of opioid addiction; (h) CMEs promoting the use of opioids to treat chronic non-cancer pain; (i) promotion of misleading scientific studies regarding the safety and efficacy of opioids

for long-term treatment of chronic non-cancer pain; (j) misuse and promotion of data to mask the true safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including rates of abuse and addiction and the lack of validation for long-term efficacy; (k) misleading statements in education materials for doctors and staff across the United States and in Alaska under the guise of educating them on new pain standards; (l) in-person detailing; and (m) withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs.

b. Defendant Endo made and/or disseminated deceptive statements, including, but not limited to, the following: (a) false patient education materials; (b) advertising the ability of opioids to improve function long-term and the efficacy of opioids long-term for the treatment of chronic non-cancer pain; (c) promoting chronic opioid therapy as safe and effective for long term use for high- risk patients; (d) creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse; (e) concealing the true risk of addiction and promoting the misleading concept of pseudo-addiction; (f) promoting an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (g) secretly funding pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat

chronic non-cancer pain; (h) funding pro-opioid pain organizations responsible for egregious misrepresentations concerning the use of opioids to treat chronic non-cancer pain; (i) downplaying the risks of opioid addiction in the elderly; (j) CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (k) misleading scientific studies concluding opioids are safe and effective for the long-term treatment of chronic non-cancer pain and quality of life, while concealing contrary data; (l) funding and promoting pro-opioid KOLs concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudo-addiction; (m) manipulation of data regarding safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and (n) in-person detailing.

c. Defendant Janssen made and/or disseminated deceptive statements, including, but not limited to, the following: (a) patient education materials containing deceptive statements regarding the suitability, benefits, and efficacy of opioids; (b) stating that opioids were safe and effective for the long-term treatment of chronic non-cancer pain; (c) stating that opioids improve quality of life, while concealing contrary data; (d) concealing the true risk of addiction; (e) promoting the deceptive concept of pseudo-addiction; (f) promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious,

and concealing this information; (g) presenting to the public and doctors an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (h) funding pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (i) funding pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain; (j) using CMEs to promote false statements concerning the use of opioids to treat chronic non-cancer pain; and (k) in-person detailing.

d. Defendant Cephalon made and/or disseminated untrue, false, and deceptive statements including, but not limited to, the following: (a) minimizing the risk of opioid addiction; (b) promoting the deceptive concept of pseudo-addiction; (c) advocating the use of opioids for chronic non-cancer pain; (d) funding misleading CMEs, KOL doctors, and pain organizations; (e) minimizing the addictiveness of Cephalon's potent rapid-onset opioids; and (f) promoting the suitability of Cephalon's rapid-onset opioids to general practitioners, neurologists, sports medicine specialists, and workers' compensation programs.

e. Defendant Insys made and/or disseminated untrue, false, and deceptive statements including, but not limited to, the following: (a) minimizing the risk of opioid addiction; (b) promoting the deceptive concept of pseudo-addiction; and (c) advocating the use of opioids for chronic non-cancer pain by funding

pain organizations and KOLs. Further, Insys, through its sales representatives and other marketing efforts, deceptively promoted Subsys as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence for such uses, and misrepresented the appropriateness of Subsys for treatment of those conditions. Insys further implemented a kickback scheme wherein it paid prescribers for fake speakers programs in exchange for prescribing Subsys.

f. Defendants Actavis and Mallinckrodt made and/or disseminated deceptive statements, including, but not limited to, the following: (a) promotion of use of opioids to treat chronic non-cancer pain to prescribers throughout the country and in Alaska through in-person detailing; (b) advertising that opioids were safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improved quality of life; and (c) advertising that concealed the risk of addiction in the long-term treatment of chronic non-cancer pain.

450. Manufacturer Defendants knew or reasonably should have known that their statements were untrue, and they failed to correct these misrepresentations and omissions. The misrepresentations and omissions were recklessly or negligently made.

451. Manufacturer Defendants made those misrepresentations and omissions in an intentional effort to deceive health care providers, physicians, and the general public throughout the United States and Alaska. Manufacturer Defendants intended that healthcare providers, physicians, and the public would rely on these statements and omissions.

452. Manufacturer Defendants knew or reasonably should have known that the statements and omissions would and did, in fact, deceive physicians, health care providers, their patients, and the public throughout the United States, including Alaska, including physicians and other health care providers serving KANA and its patients. These deceptive acts had the intent and effect of inducing over-prescription, over-reliance, and over-use of prescription opioids.

453. As a direct and proximate result of Manufacturer Defendants' misrepresentations and material omissions, KANA has suffered and continue to suffer damages in an amount to be determined in this litigation.

COUNT 9: VIOLATIONS OF THE ALASKA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION ACT
AS 45.50.471, *et seq.*
(Against All Defendants)

454. KANA incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

455. The Alaska Unfair Trade Practices and Consumer Protection Act is codified at AS 45.50.471 *et seq.* (UTPA).

456. The UTPA prohibits unfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce.

457. All Defendants are engaged in trade or commerce in the State of Alaska.

458. Defendants violated the UTPA by engaging in deceptive trade practices through the marketing, advertising, and distribution of opioids. These violations include:

a. Representing that prescription opioids have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have, in violation of AS 45.50.47 l(b)(4);

b. Disparaging the goods, services, or business of another by false or misleading representation of fact, in violation of AS 45.50.471(7);

c. Engaging in other conduct creating a likelihood of confusion or of misunderstanding and which misled, deceived, or damaged a buyer or a competitor in connection with the sale or advertisement of goods or services, in violation of AS 45.50.471(b)(11); and

d. Using or employing deception, fraud, false pretense, false promise, misrepresentation, or knowingly concealing, suppressing, or omitting a material fact with intent that others rely upon the concealment, suppression, or omission in connection with the sale or advertisement of goods or services, in violation of AS 45.50.471(b)(12).

459. The violations include, but are not limited to, deceptively and misleadingly:

a. Denying that pain patients would become addicted to opioids;

b. Omitting that opioids are highly addictive and may result in overdose or death;

c. Claiming that signs of addiction were "pseudo-addiction" reflecting undertreated pain, and should be responded to with more opioids;

d. Claiming that the risk of addiction to opioids could be managed and avoided through risk screening tools and other strategies;

e. Claiming that opioid doses can be increased, without disclosing the greater risks of addiction, other injury, or death at higher doses;

f. Misleadingly comparing opioids and NSAIDs, including overstating the risks of NSAIDs and citing risks of NSAIDs without disclosing risks of opioids;

g. Claiming that opioids are an appropriate treatment for chronic pain, and failing to disclose the lack of long-term evidence for their use;

h. Claiming chronic opioid therapy would improve patients' function and quality of life;

i. Claiming that "extended release" opioids provided long-lasting pain relief, and failing to disclose that they do not for many patients;

j. Claiming abuse-deterrent opioids reduce addiction and abuse and are safer than other opioids, and failing to disclose that they do not limit oral abuse, can be defeated with relative ease, and may increase overall abuse; and

k. Promoting themselves as cooperating with law enforcement and taking any available steps to prevent opioid abuse.

460. These deceptive acts and practices had the capacity and tendency to deceive and were capable of being interpreted in a misleading way. In fact, these deceptive acts and practices were reasonably calculated to deceive, and did in fact deceive, medical professionals and the public at large for the purposes of increasing Defendants' profits for the manufacturing and distributing of opioids.

461. Defendants' acts and practices were also unfair under AS 45.50.471(a). These acts or practices, which relied on deceptive marketing and other misrepresentation to promote addictive drugs that patients would be unable to stop taking, were immoral, unethical, oppressive, or unscrupulous, caused substantial injury to consumers and businesses, and violated public policy, including, among others, the State of Alaska's efforts to curb the opioid epidemic (which has become so severe that Governor Walker issued a Declaration of Disaster due to a statewide

"public health emergency") and the policy, reflected in 21 U.S.C. 823(e); 21 C.F.R. 1301.74(b) and AS 17.30.020 & 17.30.080, aimed at reducing diversion and requiring reporting of suspicious orders of opioids.

462. Defendants' acts and practices also constituted unfair competition. At all times relevant to this Complaint, Defendants promoted opioids as superior to other competing analgesics, such as NSAIDs, and exaggerated the risks of NSAIDs while ignoring risks of adverse effects of opioids.

463. As a direct result of the foregoing deceptive acts and practices, Defendants obtained income, profits, and other benefits that they would not otherwise have obtained.

464. KANA has suffered actual damages, including an ascertainable loss of money or property, as a result of Defendants' conduct, in violation of AS 45.50.471. KANA has paid significant sums of money treating eligible patients for opioid-related conditions, and has incurred other costs to address the opioid epidemic as described in this Complaint.

465. Pursuant to A.S. 45.50.531 and A.S. 45.50.537, KANA is entitled to actual and treble damages in amounts to be determined at trial, attorneys' fees and costs, and other relief the court considers necessary and proper.

COUNT 10: STRICT PRODUCTS LIABILITY
DESIGN DEFECT AND FAILURE TO WARN
(Against Manufacturer Defendants)

466. KANA incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

467. At all times material and relevant to this action, Manufacturer Defendants' opioids were defective in design and failed to perform as safely as an ordinary consumer would

expect when used in an intended or reasonably foreseeable manner because: (1) Manufacturer Defendants' opioids carried far greater risk and actual rate of addiction than the public was lead to believe; (2) Manufacturer Defendants' opioids failed to provide functional improvement for chronic pain patients and caused side effects, including addiction, that diminished their function and quality of life; and (3) Purdue's OxyContin failed to provide the 12-hour relief promised, and its end-of-dose failure fueled addiction and abuse.

468. Under the circumstances, which include Manufacturer Defendants' unfair and deceptive marketing and their failure to change their opioids' labels to account for post-marketing information, the Manufacturer Defendants failed to provide adequate warnings that: (a) clearly indicated the scope of the risk or danger posed by their opioids; (b) reasonably communicated the extent or seriousness of harm that could result from this risk or danger; and (c) were conveyed in a manner that would alert a reasonably prudent person.

469. Manufacturer Defendants actually knew of the defective nature of their opioids, but continued to market and sell them without proper warning, and with misrepresentations and omissions that contradicted and undermined their drug labels, in order to increase sales and profits, in conscious disregard for the foreseeable harm caused by these drugs.

470. Manufacturer Defendants knew their opioids would be used by the consumer without inspection for defect and that physicians, health care providers and patients would rely on Defendants' representations that the product was safe.

471. As a proximate cause and legal result of Manufacturer Defendants' opioids' failure to perform as reasonably expected and Manufacturer Defendants' failure to appropriately

warn of known and reasonably knowable dangers associated with the use of their opioids, KANA has suffered and will continue to suffer damages as outlined in this Complaint.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff respectfully requests judgment in its favor granting the following relief:

a) Entering Judgment in favor of KANA in a final order against each of the Defendants;

b) An award of actual, compensatory, consequential, and incidental damages in an amount to be determined at trial;

c) An award of all damages resulting from Defendants' violation of 18 U.S.C. § 1962(c) and (d), including prejudgment interest, the sum trebled pursuant to 18 U.S.C. § 1962(c);

d) An Order obligating Defendants to disgorge all revenues and profits derived from their scheme;

e) An Order ordering that Defendants compensate KANA for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

f) An Order ordering Defendants to fund an "abatement fund" for the purposes of abating the public nuisance;

g) Injunctive relief prohibiting Defendants from continuing their wrongful conduct;

h) An Order that the conduct alleged herein violates the Alaska UTPA and that KANA is entitled to treble damages pursuant to the Alaska UTPA;

i) An award of the Plaintiff's costs, including reasonable attorney's fees, pursuant

to 18 U.S.C. § 1964(c) and/or any applicable provision of law, including the Alaska UTPA;

j) Pre- and post-judgment interest as allowed by law; and

k) Any other relief deemed just, proper, and/or equitable.

PLAINTIFF DEMANDS A JURY TRIAL ON ALL CLAIMS SO TRIABLE

DATED: October 15, 2018

By: s/ Geoffrey D. Strommer

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